The Victorian Streamlined Review Process and the National Mutual Acceptance (NMA) Streamlined Review Processes

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Streamlined Ethical Review Processes:

- Currently there are three formal streamlined ethical review processes:
  
  - **SERP**: Streamlined ethical review process
  
  - **NMA**: National Mutual Acceptance
  
  - **The National Approach**: Formerly HoMER
Streamlined Processes: SERP

• Victorian streamlined ethical review process
  – Initially for clinical trials
  – From January 2015, any form of human research eligible

• 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)

- Currently only clinical trials or studies related to clinical trials are eligible

- 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
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 Authorization

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

• Site Authorisation
  – Given by Institution
  – Accept ethics approval
Ethics Approval versus Site Authorisation

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

- **Co-ordinating (Lead) Principal Investigator**
  - For non-clinical trials, this is the first Principal Investigator listed in the NEAF

- **Site Principal Investigator**

- These are only administrative roles for the purposes of the ethics and site authorisation/governance review processes
Submission to Reviewing HREC

- **Co-ordinating Principal Investigator** appointed for ethics application covering all Sites in application
  > Submits initial ethics application
  > List of Sites should not be a ‘wish list’.
    - Only list Sites that have agreed to participate at the time of the review
    - Can add other Sites later via an amendment application
  > Liaises with Reviewing HREC for the initial and post-approval applications
  > 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
Lead Site versus Accepting 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, eg training in streamlining)
  - 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, VSM, 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, submit via Online Forms, upload into ERA)
  - Ethics approval certificate issued
  - At Alfred Health, governance review done concurrently
Participant Information & Consent Forms (PICFs) and Patient Brochures

- Please use NHMRC PICF templates

- Require a Master PICF or Patient Brochure

- Master PICF or Patient Brochure should be a template for all Participating Sites to complete Site specific details.
  - Include clear instructions using italics, brackets, different coloured text so Sites know which sections can be altered.
  
>   [insert name], [insert number], [insert institutional logo], etc

  - Include a version number and/or date

  - Make provision for a Local Governance date in the footer
Participant Information & Consent Forms (PICFs) and Patient Brochures

- Optional sections are allowed in the Master documents
  - Must include instructions

Example:
For information about the registry or to opt-out from the registry, please telephone 1800 800 800

For complaints please contact [either, retain if Local Complaints contact required]:
Reviewing HREC: The Alfred Hospital Ethics Committee, Ms Emily Bingle,…..

*Please delete this section if not required.*

Or
Local complaints person: [Name],[Position], Tel: [insert number]
Participant Information & Consent Forms (PICFs) and Patient Brochures

- Require a local Site version of the Master PICF or Patient Brochure for site authorisation
  - Do not alter the version or date of the PICF or Brochure
  - Show tracked changes from Master
  - Insert the Local Governance date
Ethics Approval versus Site Authorisation

- **Site Authorisation**
  - Given by Institution
  - Accept ethics approval
  - Is the study appropriate and complies with Institution’s strategic plan? Is there reputational risk?
  - Are appropriately qualified staff involved?
  - Will training be required and provided?
  - Are there adequate resources: funding, time?
  - Legal: complies with relevant legislation? Agreements?
  - A site authorisation letter issued
  - Cannot start before site authorisation granted.
  - **Whilst there are SOPs and standard forms, the requirements for site authorisation may vary from site to site**
Researchers can participate in one of two capacities for each study:

- **Site Principal Investigator** required at each Site takes responsibility for conduct of the study at the Site
  > Liaises with:
  >   - Co-ordinating Principal Investigator
  >   - Institutional Research Governance Office (RGO)
  > Submits initial and amendment applications 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
Ethics Approval versus Site Authorisation

• 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
Ethics Approval versus Site Authorisation

• If you are the Accepting Site:
  – In addition to the ethics application, also 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 or Patient Brochure
      – 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
Ethics Approval versus Site Authorisation

• If you are the Accepting Site:
  – Require site assessment submission (continued):
    > Resource Centre Declarations – Please specify if you will **not** be using certain services (eg central laboratory rather than Alfred Pathology)
      – IT sign-off
    > Budget
    > Legal documents:
      – Agreement
      – Insurance certificate
Amendments

• All amendments apart from changes to research personnel are to be approved first 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)
  – Amendment approval certificate issued.
Amendments

• Submission for Site Authorisation:
  – Provide the amendment approval certificate, amendment application form and associated documents submitted to the Reviewing HREC to Research Governance Office
  – Site authorisation can only occur after ethics approval by the Reviewing HREC

  – PICFs or Patient Brochures:
    > 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 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 or Patient Brochure:
    > Submit tracked from Master PICFs
    > Keep the version and date unchanged
    > Insert Local Governance date in footer
  – Amendment authorisation issued
• Once the application has been approved, other Sites can be added via an amendment application

• An application can be converted from a single site application to a streamlined application:
  – Done via an amendment application
  – Study must have been reviewed and approved after the date of commencement of streamlined process, for non-clinical trials from January 2015
  – Needs to have been reviewed by a certified HREC

• Proposal for scope of eligible applications for NMA to be expanded in 2016
  – Unclear if retrospective conversions will be allowed, namely can a SERP application approved in 2015 be converted to NMA in 2016
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
Other Considerations

• Streamlining of non-clinical trial applications is new to the Office and researchers

• Difficulty with ‘one size fits all’ approach initially created for clinical trials but work with Victorian Department of Health, HRECs and RGOs to find solutions

• The Ethics & Research Office is not a portal to the hospital

• Essential to liaise with Site Principal Investigators and Site Research Governance Offices (RGOs) to ensure requirements are met

• Further streamlining?:
  – Possibility of providing a combined annual progress report across sites
  – Agreement template for registries accepted across the NMA States
Thank You!