Streamlined Ethical Review Process

Submitting an Application as a Reviewing Site

Katja Loewe, Alfred Health
Singe site vs. Streamlined

Ethics review and site authorisation (governance) concurrently at each site

Single ethics review by one accredited HREC; site authorisation (governance) at each participating site
**Ethics** vs. **Governance**

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

**Ethics approval certificate/letter**

**Governance/Site Authorisation**
- Given by Institution
- Accept ethics approval
- Is the study appropriate?
- Adequately qualified staff involved?
- Adequate resources?
- Legal documents

**Site Specific Authorisation letter**
**Reviewing vs. Accepting**

**Reviewing**

- Lead Site: Coordinate study
- Ethics review by Alfred Hospital Ethics Committee
- Ethics review and governance assessment concurrently at AH
- Once ethical approval given application for governance authorisation at other sites, even if governance at AH outstanding
- Study cannot commence until governance authorisation given

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

**Accepting**

- Ethics review by external HREC
- Submission for governance authorisation once ethical approval given, but preparation of governance documents can commence before that
- Study cannot commence until governance authorisation given

http://www.alfredresearch.org/governance/SSA.htm

**Training:** 17 Sep 2015
Responsibilities of Lead Site

- Conduit between the Reviewing HREC and Participating Sites
- Submits initial and subsequent applications and correspondence (amendments, IBs) to the Reviewing HREC for ethics approval
- Forwards relevant approvals, documents, correspondence to the Accepting Sites
- Coordinates submission of progress reports, SAEs, protocol deviations/violations etc. to the Reviewing HREC
SERP (VIC) vs. NMA (interstate)

**SERP (VIC)**
- Victorian Streamlined Process
- Reviewing/Lead HREC is accredited (NHMRC, CCCTR)
- All Sites within Victoria
- Research to be conducted in publicly funded health services

**NMA (interstate)**
- South Eastern Seaboard Streamlined Process
- Reviewing/Lead HREC is accredited (NHMRC, CCCTR if VIC HREC)
- All sites within Victoria, NSW, Queensland and South Australia
- Research to be conducted in publicly funded health services
SERP (VIC) vs. NMA (interstate)

All human research
- As defined in the National Statement on Ethical Conduct in Human Research 2007
- Includes low and negligible risk review

Interventional research
- Drug/device trial, radiation therapy, surgery, treatment or diagnostic procedure
- Studies associated with ongoing activities relating to trials that have been conducted
- May include post-trial activities such as observational research and evaluation of a trial, developing a registry and other post-marketing surveillance activities
SERP (VIC) vs. NMA (interstate)

Exceptions

- CTs involving persons in custody or staff of the jurisdictional Justice Health departments
- CTs specifically affecting the health and wellbeing of Aboriginal people and communities
- CTs requiring access to state-wide data collections
- CTs involving access to coronial material
- Clinical trials of supportive care and psycho-oncology
- Ph. 0 and 1 CTs (SA only)
SERP (VIC) vs. NMA (interstate)

Instructions, SOPs, links to Online forms and templates on Department of Health and Human Services Websites

Clinical trials

Research & Low risk projects

Clinical trials

Instructions, SOPs, links to Online forms and templates on Department of Health and Human Services Website
Submission of Streamlined Application as Reviewing Site

• If you have not prepared a streamlined application yet, have not attended training or have questions prior to submission call the Office

• Read ‘The Alfred Streamlining Ethical Review Guide’

• Call the Victorian Central Allocation System (CAS) prior to submission to us to allocate application to an HREC and obtain HREC number (e.g. HREC/15/Alfred/5 to be included on application docs; different to local project number)

• If project involves ionising radiation a Medical Physicist Report needs to be submitted for each site (initialise these before submitting)

• If project is a first-time-in-human study – as usual submit protocol and IB asap to the Office

• Upload documents into Onlineforms: 
https://ethicsform.org/au/SignIn.aspx
Submission of Reviewing Streamlined Application

Ethics review
- NEAF
- VSM
- NSW Privacy Form (if NSW sites)
- Master PICFs
- Master of any document containing site-specific details (e.g. ID card)
- Protocol, IB
- Legal docs (CTN(s), insurance certificate, standard indemnity for each site, HREC review only indemnity listing all external sites)

Governance Authorisation
- Site Specific Assessment Form
- Alfred-Specific Form
- Alfredised PICFs
- Other Alfredised documents (e.g. ID card)
- Budget
- Resource Centre Declarations
- Payment form
- Contract, approved schedule 4/7 wording, (checklist)

Ethics review and governance assessment concurrently at AH
Submission of Reviewing Streamlined Application

Ethics review & Governance authorisation

- Victorian Low and Negligible Risk (LNR) Form
- LNR Site Specific Assessment Form
- Alfred Specific LNR Form
- Master Participant Information and Consent Forms/Sheets/Opt-out information
- Alfredised Participant Information and Consent Forms/Sheets/Opt-out information
- Proposal, Data collection forms, advertisements, surveys etc.
- Biospecimen Addendum (if applicable)
- Resource Centre Declarations (if applicable)
- Ethics & Governance Fee payment form
- Legal Documents – electronically and in hard copy as relevant

http://www.alfredresearch.org/ethics/applicat/LowRisk.htm
NEAF

- Include HREC number (page 1)
- Coordinating Principal Investigator (Chief researcher) appointed for application
- Site Principal Investigator required at each site, who takes responsibility for conduct of the trial at that site
- Ensure all sites for which ethics review is requested are listed underneath reviewing HREC in section 4
- Keep in draft when first submitting as revisions not possible once finalised

1If ‘clinical research’ is not applicable to the study and the field has therefore not been indicated (section 5), the field for ‘Chief Researcher’ is not populated. In this case the first person listed under Principal Investigator is assumed to be the Chief Researcher for the purpose of the application.
Participant Information & Consent Forms

• Use **NHMRC PICF templates**

• **Master Participant Information & Consent Form for each PICF** (Main, Genetic, Biomarker, Pregnancy, etc.)
  – Template for all participating sites to complete
  – Replace site-specific information with instructions, e.g. [Insert institution], [Insert name]

• **Footer**
  – Include Master version number and date
  – Include Local Governance date (version number not required)

Master Participant Information Sheet/Consent Form Version [Insert version] dated: [Insert date]
Site: [Site Name] Local governance date: [Insert date]
Participant Information & Consent Forms

• Insert wording that is applicable for different sites along with instructions
  – Different radiation risk wording
  – Different procedures, e.g. protocol allows for MUGA or ECHO

Example:
Radiation procedure SOC at all sites but site A; radiation risk wording in PICF required for site A only

Insert the following wording for site A; remove for all other sites. Remove these instructions as well.
This research study involves exposure to a small amount of radiation…
Participant Information & Consent Forms

• Local Governance Date
  – Required for governance authorisation
  – During the initial application review phase should be updated as the date of the PICF is updated or left until final version of the PICF is available
  – Local Governance Date should not precede the date of the approved PICF
  – Should be updated when PICF is revised in amendment applications

Exception: Changes to research personnel
  – Version and date of PICF should remain the same
  – Local Governance Date should be altered only
**Participant Information & Consent Forms**

- “Alfredised” PICFs of each Master PICF for governance authorisation
  - Master PICF populated with Alfred Health details (local researchers, contact details etc.)

- “Alfredised” PICFs
  - Data to be kept at least 15 years upon completion of the trial (however ethics documents should state indefinite data storage at Alfred Health)
  - Complaints contact person, Reviewing HREC, Local HREC Office contact: Ms Emily Bingle, Governance Officer, Alfred Health, Tel: (03) 9076 3619, Email: research@alfred.org.au
Amendments

• All amendments apart from changes to research personnel other than PI are to be approved by the Reviewing HREC
• Amendments require both ethics approval and site authorisation before implementation – done simultaneously at AH
• Documents
  – Streamlined Amendment Application Template
  – Submit tracked amended and/or additional documents
  – Submit tracked Master and Alfredised PICFs
  – Submit any relevant legal and regulatory documents
  – Upload documents (apart from financial documents: budget, ASF, Agreement) into Online Forms
  – Submit Amendment fee payment form
  – For IBs/DSUR: Use Streamlined Amendment Application Template or AH Review of Updated Investigator’s Brochures Form/Review of DSUR form if AH is the Reviewing HREC
Progress Reports

• Due on anniversary date of ethics approval on certificate issued by the Reviewing HREC, not Site Authorisation date
• Use the streamlined progress report form
• Follow submission instructions of Reviewing HREC
• Responsibility of Coordinating Principal Investigator to organise 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)

- Use the streamlined AE/SAE and SUSAR/USADE forms
- Observe requirements of Reviewing HREC (e.g. reporting requirements)
- The Alfred Hospital Ethics Committee requires all that have a material impact on the continued ethical acceptability of the research to be reported
- To be submitted by each site via the Coordinating Principal Investigator to the Reviewing HREC
- Each site PI to submit to their own SAE report to their own Research Governance Office according to their site requirements
- Alfred Health requires all local SAEs to be reported

SUSARs = Suspected Unexpected Serious Adverse Reactions
USADEs = Unanticipated Serious Adverse Device Effects
Protocol deviations/violations

• Use the **streamlined template**
• To be submitted by each site via the Coordinating Principal Investigator to the Reviewing HREC
• Follow the submission instructions of the Reviewing HREC
• Each site PI to submit the report to their own Research Governance Office as well
A few scenarios…

Do all changes to the PICF require the version and date to be revised?

**Changes to research personnel**
- Version and date of PICF should remain the same
- Local Governance Date should be altered only
A few scenarios…

Another site performs a different procedure (in line with the protocol) than what is stated in the Master PICF. What do you do?

Submit an amendment to the Reviewing HREC requesting the revised PICF to be approved that contains the relevant wording along with instructions.

Insert the following wording for site A; remove for all other sites. Remove these instructions as well.

This research study involves exposure to a small amount of radiation…

Since an updated Master PICF needs to be authorised by each site, it might be an option to submit a Site Master PICF instead of revising the Master PICF if the change affects one site only.
A few scenarios…

Can you add sites after the study has been approved?

Yes, via an amendment to the Reviewing HREC. Also submit HREC review only indemnity (electronically and hardcopies), standard indemnity between new site and sponsor (electronically only) (and CTN).

The TGA has switched to an online submission process, removing the need for paper CTNs. For commercially sponsored studies the sponsor will submit the CTN online. Check our website for updates regarding any documentation that may be required for submission to us.
A few scenarios…

Can you convert a study to a streamlined application after it has been approved?

Yes, via an amendment to the HREC who approved the study, if the study has been reviewed after the date that the relevant streamlined approach had been implemented.

For example: To convert a study from single site to NMA (interstate streamlined process), the ethics review would have need to occurred after 01 Nov 2013. Retrospective conversions of studies to NMA assessed before this date are not possible.

Please note the fees for conversions to the streamlined process.
A few scenarios…

Can the responsibility of lead site be transferred to another site?

Yes, via an amendment to the Reviewing HREC.
A few scenarios…

The streamlined approach is open to research to be conducted in publicly funded health services. Can private sites be included/added as sites under the streamlined process?

Yes, but the private site is responsible for the authorisation and the monitoring of the study.
Questions?