easternhealth

Guidelines for Governance Only Submissions

(Streamlined Ethical Review Process and multi-site Low Risk)

Last updated 8 August 2017

This guide is subject to revision. The latest version is available online:
easternhealth.org.au

Guidance for research where ethical approval has been granted by a NHMRC Certified HREC. Victorian public health organisations have a formal agreement with the Department of Health and Human Services regarding their participation in the streamlined system.

Introduction

National Mutual Acceptance of scientific and ethical review for multi-centre clinical trials conducted in publicly funded health services is based on standard principles for operation. The success of the streamlined ethical review process is dependent on investigators, trial coordinators, sponsors, Contract Research Organisations (CRO) working with research governance officers to use approved forms and templates.

Contact Details

Submissions are to be made electronically to the email address: ethics@easternhealth.org.au.
Required original documents with wet-ink signature are to be sent to the address below:

Office of Research and Ethics
Level 2, 5 Arnold Street
Box Hill VIC 3128
Telephone: 9895 3100

Fees

Where a fee is payable, refer to the fee schedule below. Fees for non-commercially funded studies are determined by total project funding available. Applicants must follow Fee Notification Advice and email ethics@easternhealth.org.au. An invoice will be emailed to applicants.

Commercially funded research projects	**Fee**	**GST**	**Total**
New study submission	$5,500	$550	$6,050
Addition of a Sub-study	$2,000	$200	$2,200
Protocol Amendment	$650	$65	$715
Investigator Brochure changes	$100	$10	$110
Projects externally initiated by non-Eastern Health researchers (including where Eastern Health researchers are listed as associate researchers)			
New Study Submissions (with no commercial funding)	$600	$60	$660
Projects from researchers from affiliated university departments (La Trobe: Allied Health; Deakin: Nursing; Monash: Medicine, Nursing and Health Sciences) with no external funding			
New Study Submissions	$600	$60	$660
Projects from researchers from affiliated university departments (La Trobe: Allied Health; Deakin: Nursing; Monash: Medicine, Nursing and Health Sciences) with no external funding			
New Study Submissions	$250	$25	$275

Governance Review Application

Multi-centre projects with ethics approval through a central HREC (Streamlined Ethical Review Process SERP or National Mutual Acceptance NMA).This applies where a research project is to be conducted at Eastern Health but the application is reviewed and approved by one of the central reviewing HRECs.

Information and instructions from the **Department of Health Clinical Trial Research web-site** (https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research) is relevant to your submission. Use a Research Governance Checklist available from the above site and submit as per table below.

The Governance submission consists of a range of documents. A Site Specific Assessment (SSA) form must be submitted via Online Forms for review. In addition, a set of all relevant application documents as submitted and approved by the reviewing HREC as well as Site Specific Documents (Participant Information and Consent Forms, flyers, etc.) including Eastern Health logo and Eastern Health site and contact details should be submitted for review.

It is a requirement that all agreements are submitted to the Office of Research and Ethics prior to Executive Director of Research and Medical Services sign-off.

Eastern Health Contact Person

An Eastern Health employee should be nominated as a contact person in ALL projects undertaken at Eastern Health. An Eastern Health contact person who is involved in the project will be listed as, at the very least, an associate researcher. Their role is to provide expertise in a discipline relevant to the project, local knowledge that can facilitate the conduct of the research. The Eastern Health contact person should be regularly updated of study progress.

All documents pertaining to the application are required to be submitted electronically to ethics@easternhealth.org.au as attachments to an email or via a USB.

Only documents with original signatures are submitted in hard copies. These are: Site Specific Assessment (SSA) form, Research Agreements or Clinical Trial Agreements, Clinical Trial Indemnity forms and confidentiality agreements for non-Eastern Health research personnel.

The application will be reviewed within the Office of Research and Ethics and is not allocated to a meeting.

Research can only commence once written project authorisation is received by the research team.

Application documents for governance review submitted electronically
Research governance cover letter signed by Principal Investigator
Application Fee (Submit Fee Notification Advice)
Site Specific Assessment Form
Human Research Ethics Committee Approval correspondence

Set of the documents as approved by the Reviewing HREC and listed on the approval letter:
• HREA (NEAF being replaced September 2017)
• Victorian Specific Module (VSM)
  ○ If required, Use of Ionising Radiation
  ○ Medical Physicist Report
• Study Protocol
• Investigator Drug Brochure
• Master Participant Information and Consent Forms
• Questionnaires
• Data Collections Forms
• Patient Material

Eastern Health specific documents, e.g. Participant Information and Consent Form (PICF).
EH PICF Must have:

- EH Logo
- EH Investigators' Contact Details
- EH Hospital Site where research project is being conducted
- EH Contact for Complaints (Office of Research and Ethics, Phone: 03 9895 3398, or email: ethics@easternhealth.org.au)
- Version number and date in the document footer as per format below:
  Eastern Health Participant Information and Consent Form version X dated DDMMYYYY
  Based on Reference to approved Master including version number and date

Current Insurance Certificate:
Insurance cover must be listed in Australian Dollars
Insured must have an Australian address
It is preferred that the IC lists a study ID (Title or Protocol number)

Curriculum Vitae
Applies to researchers who have not submitted a CV to EHHREC in the last two years (internal or external).
CV should be one to two pages only, to include:

- relevant professional registration
- formal qualifications
- relevant experience

Do NOT include an extensive publications list.

Application documents for governance review submitted in hard copy and electronically

Site Specific Assessment Form including wet-ink signatures

Clinical Trial Research Agreements
Medicines Australia approved templates will not require EH legal review.
Other Research Agreements may require EH legal review. Please send a draft to the Office of Research and Ethics for pre-review before signatures are sought.
Please submit a minimum of 3 originals signed by the sponsor/CRG. Eastern Health will retain one fully signed original after final sign off.

Material Transfer Agreements
Where research involves the transfer of blood or tissue from Eastern Health to an external organisation a Material Transfer Agreement (MTA) may be required. An outgoing MTA should be used when Eastern Health is providing materials to an external organisation. An incoming MTA is provided by the relevant institution to an Eastern Health researcher requesting materials from an external source.
Please submit a minimum of 3 originals signed by the collaborating institution and investigator. Eastern Health will retain one fully signed original after final sign off.

Indemnity Forms
Only approved templates from Medicines Australia website will be accepted.
Please submit minimum of 3 original documents signed by the external Sponsor. Eastern Health will retain one fully signed original after final sign off.

Confidentiality Agreement for non-Eastern Health employees with wet-ink signatures

Post Approval Requirements

Documents should be submitted electronically to ethics@easternhealth.org.au

Amended documents can only be implemented at Eastern Health after approval from the reviewing HREC. These documents must be authorised by the Office of Research and Ethics before being implemented at site:

- Research protocol
- Investigator's Brochure updates
- Participant information sheets and consent forms

Research tools such as surveys, questionnaire, diaries, etc.

Submission of post-approval documents only **AFTER APPROVAL** by reviewing HREC

Electronic submission
Eastern Health local Serious Adverse Event (SAE) • As • Submit using **AE and SAE Report form** with the following inclusion: ○ A summary of the event e.g. whether SAE is a pre-existing condition, if participants continue on study medication and the event outcome. ○ Confirmation of whether the SAE is a suspected unexpected serious adverse reaction (SUSAR). ○ A comment on the impact of the SAE on study conduct and signature by the Principal Investigator.
Eastern Health Site Specific Progress Reports – annual and final: A Progress Report must be submitted annually according to the reviewing HREC's guidelines and reporting calendar. Submit using **Progress Report – Site Report form**. Include information on progress to date, compliance with approved protocol and conditions of approval, maintenance and security of records, and insurance status (for commercial projects). Ongoing authorisation of project is subject to submission of a satisfactory progress report. A final progress report is required when the project is completed. Use a **Final Report form** to submit when one the following has occurred: • when the project results have been published or presented (submit publication or abstract) • data analysis is complete and a lay summary of findings is available • a 'close out' visit has taken place (for externally sponsored multi-centre project) • a project has been prematurely discontinued or withdrawn
Updated insurance certificates • submission is due when the certificate is about to expire • is submitted together with the Annual Progress Report
Hard copy submission
Clinical Trial Research Agreement addendum or amendment • Submit revised documents signed by the Sponsor in triplicate. • Submit a cover letter detailing the changes. • Eastern Health will retain one fully executed agreement after review and final sign off

The following must be reported to the Office of Research and Ethics in a timely manner:

- CTN acknowledgement
- Serious Adverse Events (SAEs)
- Protocol deviations
- Protocol violations
- Change of Personnel (Addition or departure of researchers)

CTN - TGA notification

Eastern Health contact for notices: Governance

Name of Approving Authority:	Eastern Health
Approving Authority Contact Officer:	Ms Daniela Bodemer
Position:	Research Governance and Ethics Officer
Contact Phone:	03 9895 3100
Contact Email:	daniela.bodemer@easternhealth.org.au

The Clinical Trial Notification needs to be lodged online directly with the Therapeutic Goods Administration (TGA). It is requested that the EH principal investigator forward the email confirmation from the TGA and a PDF copy of the lodged CTN to the Office for Research and Ethics (ethics@easternhealth.org.au) as soon as this is available.

Change of Personnel

The Office of Research and Ethics is required to be notified of any change of personnel (addition or departure of researchers). The form is available from the Research and Ethics website – Quick Links to Forms and Templates

Addition to the research team

- Submit a brief Curriculum Vitae (one to two pages), if not submitted in the last two years.
- External researchers (non-Eastern Health employees) must also submit a signed Confidentiality Agreement if they require access to identifiable information, e.g. patients' records.

Progress Report, Insurance Certificate and Final Project Report

A Progress Report must be submitted annually according to the reviewing HREC's guidelines and reporting calendar. At the latest Eastern Health requires progress reports to be submitted by the end of February for the preceding calendar year. On-going authorisation of a project is subject to the submission of a satisfactory progress report.

Submit using a Progress Report – Site Form (RGO) available from the DHHS Clinical Trials website: https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting

Updated insurance certificates

- submission is due before the certificate expires
- is submitted together with the Progress Report – Project Form

A Project Final Report – Site Closure Report Form must be submitted when the project is completed. Submit using a final report form when one the following has occurred:

- when the project results have been published or presented (submit with publication or abstract)
- data analysis is complete and a lay summary of findings is available
- a 'close out' visit has taken place (for externally sponsored multi-centre project)
- a project has been prematurely discontinued or withdrawn

Safety Reports

Events which are directly related to an Eastern Health site should be reported to the Office of Research and Ethics in a timely manner.

Eastern Health is required to assess safety reports impacting on medico-legal risk, the responsible conduct of research, adherence to contractual obligations or the trial's continued site authorisation and where applicable, facilitate the implementation of corrective and preventative action.

Safety Report

Report promptly using a Safety Report form with the following inclusions:

- Confirmation whether the event is a serious safety issue (SSI), suspect unexpected serious adverse reaction (SUSAR) or unanticipated serious adverse device effect (USADE)
- A summary of the event e.g. whether it relates to a pre-existing condition, if participants continue on study medication and the event outcome and the action taken
- Principal Investigator's comment on the impact of the event on study conduct
- Principal Investigator's signature

Annual Safety Report

This form should be used to provide the reviewing Human Research Ethics Committee (HREC) with a summary of the evolving safety profile of the project. It should be submitted to HREC with the Progress Report – Project Form.

(Please note *NHMRC 2016 Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* – there is no longer a requirement for investigator sites and HRECs across Australia to be notified of all individual safety reports and periodic line listing events as they occur).

Protocol Deviations or Violations

Protocol Deviation is any change, divergence or departure from the project design or procedures defined in the protocol.

Protocol Violation is a more serious non-compliance that might significantly affect the completeness, accuracy or reliability of research data or that might significantly affect a participant's rights, safety or wellbeing.

To fulfil ICH-GCP requirements, any deviations or violations of the approved protocol must be notified to the reviewing Human Research Ethics Committee (HREC) using a Protocol Deviations or Violations report form.

The sponsor must complete this report and submit to the reviewing HREC. The sponsor must provide a copy to the Coordinating Principal Investigator (CPI) and site Principal Investigators (PIs) to submit it to the Office of Research and Ethics.

Complaints

Any complaints made about a research project must be reported using a Complaint report form and include the following information:

- Who made the complaint?
- What is their relationship to the research?
- What action has been taken to try and resolve the complaint?
- What action has been taken to prevent another similar complaint?
- Is any further action required?
- Is the matter resolved?

Both hard copy and electronic files are required to be submitted.