



Human Research Ethics Committee Review

Guidelines for HREC Ethics Submissions

Last updated 8 August 2017

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

www.easternhealth.org.au

The Eastern Health Human Research Ethics Committee (EHHREC) is responsible for reviewing proposals for research to be conducted at Eastern Health. EHHREC aims to ensure that the values and principles set out in the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (*'National Statement'*) are upheld. All human research conducted at Eastern Health must be approved by a NHMRC certified HREC before commencing.

Introduction

Eastern Health Human Research Ethics Committee (EHHREC) is certified by the NHMRC. The membership is made up of experienced researchers, professional carers, pastoral carers, lay members, lawyers and a chairperson. The minimum membership quorum is stipulated by the NHMRC and ensures that projects are reviewed from several different perspectives.

Research proposals are assessed in terms of research merit and integrity, justice, beneficence and respect. The committee reviews research proposals against these values and principles to ensure that the interests of participants, researchers, the institution and the wider community are protected.

Contact details for submissions and enquiries

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 3380

Fees

Where a fee is payable, refer to the fee schedule below. 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 | | | |
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| New Study Submissions | \$250 | \$25 | \$275 |

Making an Ethics Application

The first step to making an Ethics application is determining what category your project falls into. You can do this by completing the Level of Risk Checklist. Links to all forms and templates needed to make your application can be found at [Quick Links to Forms and Templates](#).

Projects may fall into one of the following five categories:

- Quality Assurance / Audit Activity
- Negligible or Low Risk Research
- Governance Review (for multiple site projects with external ethics approval)
- Full Ethics Committee Review
- Advertising for External Research: Eastern Health recruitment only

Full Ethics Committee Review

Projects specifically targeting the following participant groups will require review by the full Ethics Committee:

- Pregnant women & human foetus
- Children & young people (under 18)
- People in dependent or unequal relationships (i.e. doctors/patients, employers/employees)
- People highly dependent on medical care unable to give consent
- People with a cognitive impairment, intellectual disability or a mental illness
- People who may be involved in illegal activities
- Aboriginal & Torres Strait Islander People
- People in other countries

Initial application

Submissions are to be made electronically via Online Forms **and** to the email address: ethics@easternhealth.org.au

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|--|
| Application documents for full ethics review All documents must include version number and date in the footer |
| Application Fee (Submit Fee Notification Advice) if applicable prior to submission. |
| Human Research Ethics Application (HREA) from September 2017 This is the main application form where researchers provide their details and project details for consideration by EHHREC. This needs to include a brief summary of the project in lay language, participant and recruitment details, as well as other relevant information. The application form need to include all necessary signatures |
| Site Specific Assessment (SSA) This must be completed for each site where the research is to be conducted. It is used to provide information relevant to Eastern Health and gain appropriate authorisation from relevant departments that may be impacted by the research e.g. Hospital Information Services (HIS), Pathology, Pharmacy, Cardiology, Radiology, wards, etc. Wet ink original signatures are required. |

Victorian Specific Module (VSM)

The Victorian Specific Module addresses legislative requirements in undertaking human research in Victoria. There are several sections and not all of them may apply to every research project.

Research proposal or protocol

Needs to include all relevant components:

- Background/Rationale
- Literature review
- Aims/ Research Questions & Hypothesis
- Methods
- Inclusion criteria
- Exclusion criteria
- Recruitment and consent process i.e. who, when, how and by whom
- Randomisation procedures (if any)
- Collection, use, storage and disposal of samples and/or data
- Confidentiality and privacy of samples and/or data
- Risks & Benefits
- Statistical analysis
- Publications and reporting of study results

Eastern Health Participant Information and Consent Form (PICF).

EH PICF must follow the template (see Quick Links to Forms and Templates) and 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

Other Documents pertaining the application (**must include version number and date in the footer**):

- Audit tool, data collection sheet or Excel spread sheet
- Questionnaire/survey
- Advertising Material

Curriculum Vitae

Applies to researchers who have not submitted a CV to Eastern Health HREC 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.

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

Eastern Health Contact Person

An Eastern Health employee should be nominated as an associate researcher or as a contact person in ALL projects undertaken at Eastern Health.

An Eastern Health contact person who is involved in the project should be listed as an associate researcher. If the contact person is not involved in the project, their role is to provide a link between the external researchers and Eastern Health, to provide local knowledge that can facilitate the conduct of the research and have expertise in the discipline relevant to the project.

The Eastern Health contact person should be regularly updated of study progress.

Governance Requirements

Outstanding governance requirements will not delay ethical review, so there is no need to wait until you have all of these documents ready to submit your application. Eastern Health HREC will review applications where governance documents follow later. However, the project will not receive final approval until all governance requirements have been met.

Any governance requirements that are outstanding at the time of initial submission should be submitted all together once they have all been gathered.

Clinical Trials Conducted under the CTN or CTX Scheme

A Clinical Trial Notification (CTN) to the Therapeutic Goods Administration (TGA) is required if your project includes one of the following:

- A product not entered on the Australian Register of Therapeutic Goods (ARTG), including any new formulation of an existing product or any new route of administration; or
- Use of a registered or listed product outside the conditions of its marketing approval.

Sponsors are required to complete an eCTN form online and submit it to TGA.

The Sponsor is the individual, company, organisation, or institution that:

- Intends to supply the goods
- Initiates, organises and supports a clinical study
- Takes overall responsibility for the conduct of the trial
- Signs either the CTN or CTX form
- Is responsible for meeting the regulatory requirements of the Therapeutic Goods Legislation

All CTN and CTX trials must have an Australian Sponsor.

Clinical trials can be divided into two groups, according to the type of Sponsor:

- The typical industry-sponsored clinical trial, where the trial is conducted by a private entity (who is commonly the holder of the 'marketing approval' of the trial product)
- The investigator initiated trial where the Sponsor is not a commercial entity, but an individual health professional or a 'not-for-profit organisation', which can be a governmental body (e.g. a public institution hospital, University, a trust, or a research group) - also called a NCT (non-commercial trial)

Eastern Health Sponsored CTN Clinical Trials (i.e. Investigator initiated trials where there is no external sponsor):

Upon receipt of the governance authorisation from Eastern Health, researchers are asked to make an appointment for clinical trials with the Manager, Office of Research and Ethics to lodge the online CTN application. This arrangement ensures that a consistent approach is used for trials where Eastern Health, through the investigator, assumes responsibility for the trial. This is an essential risk management activity and will ensure that our institution and our investigators are protected and fully

compliant with TGA and insurance requirements. The fees associated with CTN submission for such trials are carried by the department placing the application.

For Eastern Health single site submissions the CTN contact is:

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|-------------------------------------|--|
| Name of Approving Authority | Eastern Health |
| Approving Authority Contact Officer | Ms Natasha Savvides |
| Position | Research Ethics and Governance Officer |
| Contact Phone | 03 9895 3380 |
| Contact Email | Natasha.savvides@easternhealth.org.au |

Research Agreements

Please see Quick Links to Forms and Templates for the following research agreements (if required)

- Clinical Trial Research Agreement
- Material transfer Agreement
- Data Transfer Agreement
- Collaborative Agreement

Agreements need to be submitted with original signatures in triplicate to the Office of Research and Ethics. Eastern Health Executive sign-off will be sought by the Office of Research and Ethics.

Commercial project submissions must include the following:

- Clinical Trial Research Agreement (CTRA) using the latest Medicines Australia template
- Schedule 7 clauses must have been approved by the Department of Health
- Indemnity using the latest Medicines Australia template
- Insurance certificate of currency with the full legal name of the commercial sponsor organisation identical to that on the commercial indemnity certificate.

Material Transfer Agreements

Where research involves the transfer of 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.

Post Approval Requirements

Submissions are to be made electronically to the email address: ethics@easternhealth.org.au

Progress Reports

A progress report must be submitted annually by the end of each February for the preceding calendar year. Submissions are made electronically to the email address: ethics@easternhealth.org.au

Submit using a progress report form. Include information on progress to date, compliance with approved protocol, maintenance and security of records, compliance with conditions of approval, and insurance status (for commercial projects). On-going authorisation of a project is subject to the submission of a satisfactory progress report.

A **Final Report** 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

Updated insurance certificates

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

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. Events where required are to be reported on VHIMS and to the Victorian Managed Insurance Authority.

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.

Report a deviation using a Protocol Deviation or Violation Report Form if the following applies:

- the deviation leads to a Serious Adverse Event in which case submit a AE and SAE Report form

- the deviation involves a consent issue
- the deviation is considered to be a major violation, for example, a participant of child bearing potential is enrolled without a pregnancy test
- the deviation impacts on safety, patient care or study analysis
- the Principal Investigator determines that the deviation should be reported

The report must include a summary of the event, impact to study and the participants, and action planned or undertaken to prevent recurrence. The form must be signed by the Principal Investigator.

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.

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?

Post Approval Changes

Submissions are to be made electronically to the email address: ethics@easternhealth.org.au

Researchers must apply to Eastern Health HREC using an Amendment Form signed by the Principal Investigator and gain approval before they can implement any change to the following:

Protocols

Submit the revised Protocol with a summary of changes preferred. Alternatively, submit a copy showing tracked changes with 'strike-through' for deletions and underline for additions, together with a 'clean' copy. Ensure the revised document has an updated version number and date to enable version control.

Participant Information and Consent Forms (PICFs)

Submit a revised document showing tracked changes with 'strike-through' for deletions and underline for additions, together with a 'clean' copy. Ensure the revised document has an **updated version number and date** to enable version control.

Changes to PICF should not be submitted as an addendum; rather the current approved version should be revised to incorporate new information and changes

Supporting Forms

Research tools such as surveys, questionnaire, diaries, data collection form, etc.

Changes must be clearly identified to facilitate review. **Version number and date must be updated** for version control.

Change of Personnel

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 confidential information, e.g. patients' records.

Any change of personnel, including if someone leaves the study team, can be notified to Eastern Health HREC using a Change of Personnel Form. No fee applies.

Research Agreement

Submit three revised documents, signed by the Organisation, CRG and Principal Investigator. Submit a cover letter detailing the changes. Eastern Health will retain one fully executed agreement after review and final sign off.