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 3100

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.

<table>
<thead>
<tr>
<th>Commercially funded research projects</th>
<th>Fee</th>
<th>GST</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>New study submission</td>
<td>$5,500</td>
<td>$550</td>
<td>$6,050</td>
</tr>
<tr>
<td>Addition of a Sub-study</td>
<td>$2,000</td>
<td>$200</td>
<td>$2,200</td>
</tr>
<tr>
<td>Protocol Amendment</td>
<td>$650</td>
<td>$65</td>
<td>$715</td>
</tr>
<tr>
<td>Investigator Brochure changes</td>
<td>$100</td>
<td>$10</td>
<td>$110</td>
</tr>
</tbody>
</table>

Projects externally initiated by non-Eastern Health researchers  
(including where Eastern Health researchers are listed as associate researchers)

<table>
<thead>
<tr>
<th>New Study Submissions (with no commercial funding)</th>
<th>Fee</th>
<th>GST</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Study Submissions</td>
<td>$600</td>
<td>$60</td>
<td>$660</td>
</tr>
</tbody>
</table>

Projects from researchers from affiliated university departments (La Trobe: Allied Health; Deakin: Nursing; Monash: Medicine, Nursing and Health Sciences) with no external funding

<table>
<thead>
<tr>
<th>New Study Submissions</th>
<th>Fee</th>
<th>GST</th>
<th>Total</th>
</tr>
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<td>$660</td>
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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

The governance review and full ethics committee review are covered in separate guidance notes.

**Negligible or Low Risk Research**

Negligible risk and low risk research has been defined in the National Statement on Ethical Conduct in Human Research (s2.1).

**Negligible risk** applies where:
- There is no foreseeable risk of harm or discomfort
- Any foreseeable risk is no more than inconvenience

If there is any risk, even if unlikely, of more than inconvenience, the research is not negligible risk.

**Low risk** applies where the only foreseeable risk is discomfort.
If the risk of research, even if unlikely, is more serious than discomfort, the research is not low risk.

Projects specifically targeting the following participant groups should not be submitted as low risk and 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

Incidental inclusion of participants from the above categories is permissible.

Researchers are required to use the Eastern Health Low Risk Application form. Submissions are to be made electronically to the email address: ethics@easternhealth.org.au.

**Application documents for negligible or low risk review**

- All documents must include version number and date in the footer
- Application Fee (see Fee Notification Advice) if applicable (see page 4).
- Low Risk Application Form including all necessary signatures
  - All Investigators
  - Head of department (if HoD is also a researcher, sign off from HoD manager is required)
  - Supporting departments
  - Other ward/unit
  - Eastern Health contact person
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 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 spreadsheet
- 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

Research Agreements in triplicate with original signatures (if required)
- Material transfer Agreement
- Data Transfer Agreement
- Collaborative Agreement

Applications are reviewed by Eastern Health HREC Sub-committee. Refer to Sub-committee meeting dates and deadlines if necessary on Eastern Health research website.
**Eastern Health Contact Person**

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

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

**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 and compliance with conditions of approval. 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

**Reportable Events**

Researchers must notify the Eastern Health HREC immediately of any ethical issues that arise out of their research. Adverse events can arise unexpectedly and can relate to a range of impacts, such as: legal; social; economic; physical; or psychological. Where the impact is considered to be significant to the participant the research must promptly notify the Eastern Health HREC.

**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

Research tools such as surveys, questionnaires, diaries, data collection form, etc.
Changes must be clearly identified to facilitate review. Version number and date must be updated for version control.

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 confidential information, e.g. patients’ records.
Any change of personnel, including if someone leaves the study team, can be notified to EHHREC 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.

General Information

Waiver of Consent
Consent to participate in research must be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it. The requirement for consent may sometimes be justifiably waived. In this case research participants will characteristically not know that they, or perhaps their tissue or data, are involved in the research.
Only an HREC may grant waiver of consent for research using personal information in medical research, or personal health information.

To apply for a waiver of consent, researchers must adequately address 2.3.6 (a) to (i) of the National Statement and complete Health Services Commission Report Form.
**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.

**Record retrieval fees**

Retrieval of more than 10 medical records from Health Information Services (HIS) will incur a separate fee. Refer to [HIS Retrieval Fees](#) under Local Guidelines.