

Latrobe Regional Hospital Human Research Ethics Committee

Guidelines for Researchers

ETHICAL APPROVAL OF A RESEARCH PROJECT INVOLVING HUMANS

Introduction:

The Latrobe Regional Hospital's Human Research Ethics Committee (HREC) is constituted according to the National Health and Medical Research Council (NHMRC) guidelines. The *NHMRC National Statement on Ethical Conduct in Human Research* ('**National Statement**') sets out principles for the conduct of research involving humans, and gives a clear indication of the issues that HRECs will consider in determining the scientific merit of, and ethical issues raised by your project proposal.

HREC Membership:

The Latrobe Regional Hospital's Human Research Ethics Committee (HREC) has a core membership comprising:

- a Chairperson;
- a Deputy Chair;
- a member of the Latrobe Regional Hospital Executive;
- at least two members who are lay people, one man and one woman, who have no affiliation with this health service and do not currently engage in medical, scientific or legal or academic work;
- at least one person with knowledge of, and current experience in, the professional care, counseling or treatment of people;
- at least one person who performs a pastoral care role in a community;
- at least one member who is a lawyer;
- at least two people with current experience that is relevant to research proposals that are to be considered at the meetings they attend. These two members are from time to time selected from an established pool of inducted members with relevant expertise as required.

HREC Meetings:

The HREC meets six times a year. The meetings are generally held in February, April, June, August, October and December.

New applications and modifications to previously approved projects must be received by the HREC Secretary by the submission close date before the meeting to meet the agenda deadline. Late items are held over to the following meeting. Submission closing dates can be obtained from the LRH's website, intranet or by contacting the HREC Secretary (See details below).

Completing the Application:

An investigator planning a new project involving human subjects must submit a completed **Application Form** to the Human Research Ethics Committee. If the application is not complete or if necessary supporting information is not provided, **the application will be returned to the Principal Investigator.**

The application must be lodged no later than the submission close date for the next HREC meeting. The research must not start before ethical approval has been granted.

Investigators are advised that it is essential to present the project in terms which will be understood by a layperson.

Ensure that ALL questions are answered. Attachments must be labelled with the question numbers and question titles. Your application must be fully paginated (*eg Page 1 of 50*).

Your application is ready to photocopy and submit if you have:

- read the Guidelines, and the Statement
- answered every question
- attached all relevant documents
- included signature pages

Application

In general, an application for research should include:

- Latrobe Regional Hospital HREC Application Module;
- Department of Human Services Application Module;
- Statements by Heads of Department and Divisional Director involved;
- Research Project Protocol;
- Copy of research instrument to be used;
- Participant Information Sheet;
- Participant Consent form;
- Documented evidence of Scientific Merit of the project through approval from Monash University School of Rural Health, Latrobe Regional Hospital. Alternatively a certificate of HREC approval from another Tertiary Education Facility (University) Ethics Committee will be accepted as evidence.

Participant Information & Consent Form

The Participant Information and Consent Form template is available via the Department of Human Services website and is required to be placed on institutional letterhead.

Project participants are advised of the complaints process via the information and consent form for the project.

Any Researcher or individual should follow the Latrobe Regional Hospital's Complaints Policy should there be any areas of concern in relation to the research being undertaken at the Hospital.

Privacy and Confidentiality

The HREC requires investigators to preserve the confidentiality of information about research subjects, and to ensure the confidentiality of records. Confidential or personal information obtained for research projects must not be used for purposes other than those specified in the approved protocol.

Approval:

Once the application has been considered by the HREC, the principal investigator is notified of the decision in writing. Each project is allocated a registration number, which must be quoted by the principal investigator in all future correspondence. Approval will be given for a maximum of five (5) years. Approval is subject to the completion of annual reports and compliance with any other conditions imposed by the HREC. No amendments, modifications or additions may be made to the protocol without the HREC considering and approving the changes. In addition, if adverse consequences or unexpected side effects are encountered during the study, or if new data becomes available relating to any risks, the HREC must be informed as soon as possible. Any change in researchers must be notified and additional researchers must be approved by the Committee.

Monitoring of projects:

It is a requirement of the NHMRC that the Committee monitors all current research on an on-going basis. The HREC requires an annual progress report on every approved project. This report should be prepared by the principal investigator. In addition, the Committee may at any time review the project or call for an interim report.

Failure to submit may result in suspension or withdrawal of approval.

Modifications to project:

The Committee must approve any proposed amendments to the protocol. Any amendments to the project should be forwarded to the Committee for consideration. This includes personnel changes.

Annual and Final Reports:

At the completion of the research project, the principal investigator is required to submit a final report, along with any publications developed.

The Principal Investigator must submit annual progress reports to the Committee, as per the "Annual Report" template, along with any publications developed.

A Final Report must be submitted as soon as practicable when a project is completed or terminated - at the latest at the time of the next due Annual Report. Details of reason why project terminates is to be included in report.

If, after five years, the project has not been completed, a full application form must be submitted to the HREC for consideration. The HREC is obliged to withdraw approval for any project for which it has not received a satisfactory report.

Number of copies required:

One original single-sided copy **plus** fifteen double-sided stapled copies of the completed application and attachments should be forwarded to the HREC Secretary at least **four weeks before the ethics committee meeting** at which you wish it to be considered. See meeting and deadline schedule. The copies should be collated and paginated (eg Page 1 of 50).

Queries:

Any queries regarding human research projects can be directed to the HREC Secretary on (03) 5173 8811. Applications and correspondence should be sent to:

The Secretary
Human Research Ethics Committee
c/- Executive Office
Latrobe Regional Hospital
PO Box 424
TRARALGON VIC 3844

Latrobe Regional Hospital Forms:

Application forms and weblinks to templates are available on the Latrobe Regional Hospital's website (www.lrh.com.au) and Intranet. To ensure you are using the most up to date version of the forms, please always refer to the website to obtain the current version.