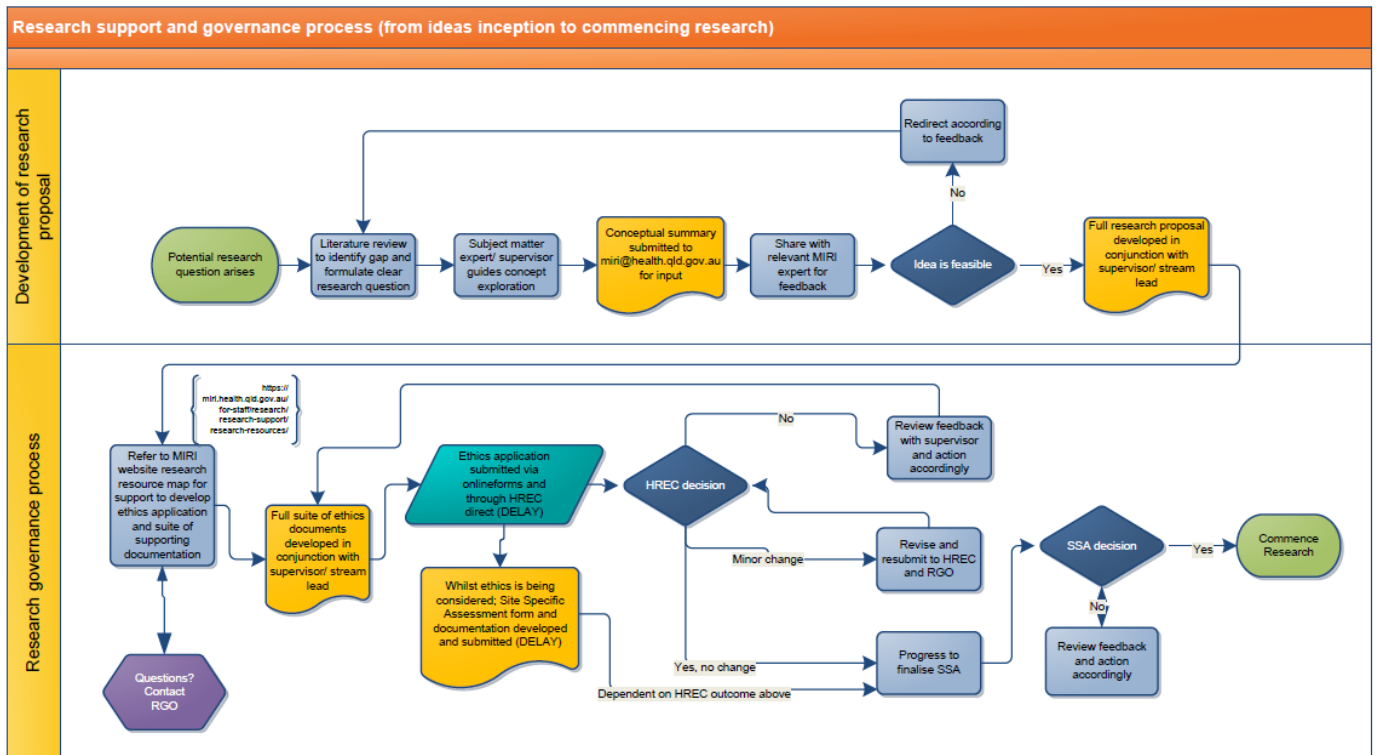


# Human Research Ethics Committee (HREC)

## Review Process

What is the process for a research project from application to commencement?



### How long will it take to get ethical approval?

All Queensland Health HRECs work on a 60 clock/calendar day timeframe from the point an application is considered valid, i.e. the time it takes to approve your research from closing date until the HREC meeting and contacting you after the meeting with the HREC decision and recommendations. The clock stops until your response to recommendations has been received and starts again on receipt.

An example of this process is outlined by [THHS HREC](#), currently the Townsville HHS HREC completes the approval process in 20 days for NEAF/HREA Applications (greater than low risk) and an average of 15 days to review and provide decision on LNR (Low and Negligible Risk with both consent and without).

Please Note: This does not include site specific assessment authorisation which is required for each site you wish to conduct your research project within Queensland Health.

## What is the length of ethical approval?

The duration of ethical decision applies for the expected duration of the project as specified in the ethics application form. This will only change if the HREC upon review or notification wish to suspend or terminate the decision, the Principle Investigator and Associates will receive notification of this decision. In other cases the Principle Investigator may wish to extend Ethical Approval to increase the number of recruited participants as an example, any/all changes must be submitted to the HREC for ethical review and approval if deemed ethically sound.

## What is the difference between Quality Activity, Low or Negligible Risk or High Risk projects?

**QA** – An activity where the primary purpose is to monitor, evaluate or improve health service delivery through a systematic review of service/s against explicit criteria.

**LNR** - Section 2.1.6 of the National Statement on Ethical Conduct in Human Research describes research as “Low Risk” where the only foreseeable risk is one of discomfort. Negligible risk research is where there is no foreseeable risk of harm or discomfort and any foreseeable risk is no more than inconvenience.

**HREA** – All other research where the risk is considered more serious than Low or Negligible risk, as outlined above.

## Do I need ethical approval to do a case study?

Any project that may be published requires ethical approval before starting the project. Researchers are advised to contact the editor of the journal in which they intend to publish, to find out specific requirements.

## What is non-identifiable data?

Non-identifiable data has no codes (e.g. UR number or other number) or links back to identifiable data. You will have no way of knowing who the data concerns from when you first begin to look at and collect this data for analysis. For example, you may ask a Clinical Information Department to run a report for you that has fields such as age (not date of birth), male or female, date of admission, diagnosis, and length of stay. This data has no identifiers and you have no way of going back to the original records.

## What is re-identifiable data?

A UR number identifies a patient because you can go back to the record. Other identifiers include pathology Vitek ID, database codes etc. Other examples are numbers given to patients involved in clinical drug trials and they are known by that number, however, they can be re-identified because the code is linked to a Hospital record.

## Waiving consent and the Public Health Act:

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 a full

Human Research Ethics Committee can grant waiver of consent, and the research must be no more than low risk. Full guidelines for waiving consent are available in Section 2.3 Qualifying or Waiving Conditions for Consent of the National Statement on Ethical Conduct in Human Research (2007):

<http://www.nhmrc.gov.au/guidelines/publications/e72-0>

After approval is granted to waive consent by a HREC, the researcher must seek approval for the release of confidential information for the purposes of research under Section 280 of the Public Health Act 2005 (PHA approval). Further information and the application form is available on the link below:

[http://www.health.qld.gov.au/ohmr/html/regu/aces\\_conf\\_hth\\_info.asp](http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp)

### **What if my project is quality assurance only?**

If a project is genuinely quality assurance then it does not need an ethical review unless it is to be published (see above). In this instance, ethical review is not required however QA activities should be registered with the Quality Improvement Unit on a QA Registry. Refer to [serviceimprovement-mackay@health.qld.gov.au](mailto:serviceimprovement-mackay@health.qld.gov.au)

### **Single ethical review for multi-centre trials:**

Queensland Health has implemented a system of single ethical review to enable multi-centre research studies to be ethically and scientifically reviewed once only. Any ethics applications for multi-centre research should be submitted an appropriate HREC.

### **Multi-centre interstate clinical trials:**

The NSW, Queensland and Victorian Departments of Health signed a Memorandum of Understanding to introduce mutual acceptance of ethical and scientific review of multi-centre interstate clinical trials undertaken by a Public Health Organisation. Each proposal for a multi-centre clinical trial conducted across the participating states will be ethically and scientifically reviewed once by an NHMRC certified Public Health Organisation HREC. Please note some exclusions apply, check the website below for further information on interstate clinical trials: [http://www.health.qld.gov.au/ohmr/html/regu/mou\\_serp.asp](http://www.health.qld.gov.au/ohmr/html/regu/mou_serp.asp)

### **What if I have already completed my project without ethical approval?**

HRECs do not grant retrospective approval. Also most journals will not publish research without ethical review. However you can complete the project again using the first study as evidence of validity and beneficence. Plan a future study to capture the data and submit for review by a HREC before starting the project. (If suitable you can use the same data collection tool, participant survey or even the same participants).

## Do I have to upload all the supporting documents onto the online forms?

Yes, this ensures that all documentation is automatically uploaded into the HREC database (AU RED) and enables the HREC to have an electronic copy of all the documentation. Supporting documents can still be uploaded even after the ethics application has been submitted to the HREC. Supporting documents can be progress reports, PICFs, annual reports, SAE reports and study amendments.

## Common problems with Ethics applications:

- Choose achievable start and end dates (allow time for HREC and RGO processing and we recommend a minimum of 1 year for project length).
- Research data should be kept according to the guidelines in the Australian Code for the responsible Conduct of Research, section 2.11:  
<http://www.nhmrc.gov.au/files/nhmrc/file/publications/synopses/r39.pdf>
- Supporting documents should have version numbers and dates.
- Head of Department sign off and/or letters of support should be signed by the appropriate financial delegate (who cannot be on the research team).
- LNR applications are encouraged to include a Peer Review from the line manager or Head of Department.
- Complete a spelling and grammar check, even get an independent person to review the submission to identify any mistakes the author may have missed.
- Include key references to support the study.
- All projects, regardless of level of risk, should have a study protocol. (The NEAF or LNR Form is not your protocol or study proposal).

## What are the recommended supporting documents for an ethics application?

- Cover letter which clearly outlines what the application is and which sites are seeking approval. It should include a list of attachments for the submission.
- Study protocol (essential for all projects).
- Participant information and consent forms.
- Data collection tools.
- For low risk, peer review from appropriate Heads of Department, (Merit, Integrity and Benefit Form)
- Current Curriculum Vitae for all researchers who have not submitted a CV within the last two years (signed and dated).
- CTN/CTX form(s), (if required).
- Investigators Brochure.
- Questionnaires/Surveys/anything given to the participant.
- Letters of invitation to participate in the study.
- Advertising materials (transcript for advertisement, brochure, webpage, poster).

- Peer review, expert independent reviews etc (highly recommended for all projects). Signature pages from the application form with “wet ink” signatures.

### Why do I need to have a peer review of my project?

Peer review is critical to provide reliable and credible research. It is difficult for authors and researchers to spot every mistake or flaw in a project document, peer review is an impartial evaluation to identify weaknesses and errors for improvement. Peer review should be an assessment of the project not a letter of support.

### Why do I need to have a Study Protocol?

A research protocol is the complete study design including aims, methodology, stats, data analysis, risks, management of risks, data safety monitoring committee and addendums such as participant information, questionnaires and other tools, standard operating procedures and day-to-day guidance for conducting the study. The NEAF, which is your “ethical application”, asks pertinent ethical questions. It is not particularly set out in a manner in which you can conduct your study and you will probably never refer to this document again, whereas a protocol forms the basis for your final study publication. Amendments and changes to your study will be made in the Study Protocol not the NEAF or LNR. Clinical trial protocol template can be found at: [http://www.health.qld.gov.au/ohmr/html/regu/gcp\\_sop.asp](http://www.health.qld.gov.au/ohmr/html/regu/gcp_sop.asp)

### Participant Information Sheets:

- Relevant and clear, written for a non-expert. (reading age approximately 12)
- Includes contact details for researchers and reviewing HREC.
- Clearly state if the consent will be for “future use of data and tissue in research”.
- Use of the NHMRC standardised PICFs is suggested. The PICF does not need to be a duplicate of the NHMRC form, but should contain all the elements of the NHMRC forms. This is the link to the NHMRC Forms site: <http://hrep.nhmrc.gov.au/toolbox/standardised-forms>

### How can I check my PICF Participant Information Sheet is at a reading age of 12 years?

In a Microsoft Word document, on the Tools menu, click Options, and then click Spelling and Grammar tab. Select the Check Grammar with spelling check box. Select Show Readability Statistics check box, and then click OK. On the Standard toolbar, click Spelling and Grammar. When MS Word finishes checking spelling and grammar, it displays information about the reading level of the document.

### Annual Reports

Researchers are required to submit an Annual Report for each research project, initially 6 months after the approval date, and every 12 months thereafter on the anniversary of ethics approval, unless otherwise

specified. Based on information received in the progress report, the HREC or RGO may elect to undertake a monitoring visit.

## **How do I make an amendment to my research project after submission and/or Approval?**

Amendments to approved research protocols must be submitted on an HREC Amendment Form to the HREC Administrator for review by the HREC (do not submit a new ethics application form). One hard copy is required of the signed HREC Amendment Form and clean and tracked versions of any updated supporting documents (eg. Participant Information and Consent Forms or Study Protocols). Executive approval of amendments may be provided between meetings by the HREC Chair, if the risk is low. Otherwise the Chair may refer an amendment to the next HREC meeting. Amendments must also be submitted to each relevant RGO for approval after HREC review.

## **How do I report an adverse event?**

An adverse event can be any unfavourable or unintended sign, symptom or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. All adverse events must be notified to the Committee as soon as possible. In addition, the Investigator must provide a summary of the adverse events, in the specified format, including a comment as to suspected causality and whether changes are required to the Patient Information and Consent Form. In the case of Serious Adverse Events occurring at the local site, a full report is required from the Principal Investigator, including duration of treatment and outcome of event. Adverse Event reporting templates are available on website.