



Queensland
Government
Queensland Health

Researcher User Guide (RUG)

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QUEENSLAND HEALTH RESEARCHER USER GUIDE

INTRODUCTION

This user guide provides information for researchers on how to obtain authorisation to commence a research project within or in association with Queensland Health. This involves a two step process.

Step 1: Seeking ethical and scientific approval of the research protocol by a Human Research Ethics Committee (HREC); and

Step 2: Completing the research governance component of a Site Specific Assessment (SSA) on-line.

Why do we need research governance?

The NHMRC "National Statement on Ethical Conduct in Human Research" (2007) and NHMRC and Universities Australia "Australian Code of Conduct for the Responsible Conduct of Research" (2007) requires institutions to establish good research governance and management practices. Research Governance is the framework for effective oversight of research, such that it meets appropriate standards of quality, safety, privacy, risk management, financial management and ethical acceptability

The **scientific and ethics review** is conducted by a HREC. The Committee is responsible for the review of the research/scientific methods, ethical standards, safety and welfare of research participants. The **research governance** component requires completion of a Site-Specific Assessment (SSA) at each participating site to determine the level of support and suitability of a research project to be conducted and completed at a site, whether that project is multi-centre or single-site.

The outcomes of the HREC review and SSA together make up the final documentation that is provided to the District CEO or delegate. These documents collectively allow for consideration of all aspects of the research project governance arrangements and will assist the District CEO or delegate's, decision on granting authorisation to conduct the research at the site.

Detailed information about the Queensland Health process for submission and authorisation of research can be obtained at the Queensland Health Research Ethics and Governance Unit website:

http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

In line with the National Statement on Ethical Conduct in Human Research 2007 Section 3.3.12 and the updated Declaration of Helsinki Section 19 if you are conducting a clinical trial (as defined by the International Committee of Journal Editors) http://www.icmje.org/#clin_trials you should register your trial on an authorised, publicly accessible clinical trial registry, prior to the commencement of the clinical phase of the trial. Researchers can register their clinical trials for free on the Australian New Zealand Clinical Trials Registry (ANZCTR) <http://www.anzctr.org.au>

Glossary

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| Chief researcher | The investigator responsible for coordinating a research project. For single centred studies the terms coordinating principal investigator, chief researcher/ investigator, site principal investigator and principal investigator are all synonymous. |
| Clinical trial coordinator | The person designated by the PI to be responsible for liaising with the HREC / research governance office(r). May also known as the site coordinator, contact person, project liaison officer. |
| Contact person | The person designated by the PI to be responsible for liaising with the HREC / research governance office(r). May also known as the site coordinator, clinical trial coordinator, project liaison officer. |
| CPI/ CI | Coordinating Principal Investigator. The investigator responsible for coordinating a multi-centre research project, and the submission and communication of all subsequent requests and notifications to the site Principal Investigators. For single centred studies the terms coordinating principal investigator, chief researcher/ investigator, site principal investigator and principal investigator are all synonymous. |
| HREC coordinator | An HREC coordinator is an employee of the institution who provides administrative support and advice on the institution's process of ethics review of research projects. The coordinator reports to the Chair of the HREC in matters related to the activities of the Committee. The terms HREC administrator, HREC coordinator and HREC secretariat are all synonymous |
| Low risk research | 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. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk |
| Minor amendment | An amendment not requiring review by a full HREC. Can receive approval outside of scheduled HREC meeting. Changes to the details of research that have no significant implications for subjects or for the conduct, management or scientific value of the study and can be regarded as minor amendments (sometimes referred to as "administrative amendments"). Examples as follows: <ul style="list-style-type: none">• Correction of typographical errors in the protocol or other study documentation• Amended contact details for the sponsor or project staff• Appointment of new support staff |

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| MCR | Multi-centre research. Research to be conducted at more than one site (this may include sites other than Qld Health sites) and within the jurisdiction of more than one HREC. eg Redcliffe / Caboolture would be considered one site and therefore single centre research however Logan / Gold Coast would be considered two sites and therefore multi centred research even though only one HREC (eg PAH) may have reviewed the project . If more than one SSA needs to be generated the research is multi centred. |
| Negligible risk research | Section 2.1.7 of the National Statement describes research as “negligible risk” where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.” |
| Principal Investigator | An investigator who acts as principal investigator at a study site i.e. the investigator responsible for the overall conduct of the research project at an individual site within a Health Service District of QH. For single centred studies the terms coordinating principal investigator, chief researcher/ investigator, site principal investigator and principal investigator are all synonymous. |
| Project liaison officer | The person designated by the PI to be responsible for liaising with the HREC / District/site research governance personnel. The terms contact person, clinical trial coordinator, site coordinator and project liaison officer are all synonymous. |
| Quality Assurance | <p>An activity where the primary purpose is to monitor, evaluate or improve the quality of health care delivered by a health care provider (an individual, a service or an organisation) is a quality assurance study. Attempts to clearly separate quality assurance from research are difficult. What really matters is that:</p> <ul style="list-style-type: none"> (a) quality assurance is undertaken for a valid purpose and its outcomes are used to improve health care; (b) those who undertake quality assurance adhere to relevant ethical principles and State, Territory and Commonwealth legislation; and (c) where quality assurance proposals could infringe ethical principles that guide human research, independent ethical scrutiny of such proposals should be sought. |
| QH REGU | Queensland Health Research Ethics and Governance Unit. |

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| Research Authorisation | Authorisation issued by the QH HSD District CEO or delegate to conduct research at the Health Service District/Site. Authorisation is contingent upon receiving HREC approval and a completed site-specific assessment. |
| RGO | Research Governance Office(r) / Function The Office or coordinated function within a Public Health Organisation which is responsible for assessing the site-specific aspects of research applications, make a recommendation to the District CEO / delegate as to whether a research project should be granted authorisation at that site, and overseeing that authorised research at the site meets appropriate standards (research governance). |
| Single-site research | Research to be conducted at one site only within the QLD public health system. If only one SSA needs to be generated the research is single site research. |
| Site Principal Investigator | An investigator who acts as principal investigator at a study site in a multi-centre research project i.e. the investigator responsible for the overall conduct of the research project at an individual site within a Health Service District of QH. For single centred studies the terms coordinating principal investigator, chief researcher/ investigator, site principal investigator and principal investigator are all synonymous. |
| Site-specific Amendment | An amendment request for an authorised research project that may be submitted by the applicant to the site/District Research Governance Office/r only (bypassing the HREC). |
| Site coordinator | The person designated by the PI to be responsible for liaising with the HREC / District/site research governance personnel. The terms contact person, clinical trial coordinator, site coordinator and project liaison officer are all synonymous. |
| 60-day clock | The period of 60 days allowed for the issue of an ethical decision on an application. For research not requiring review at a full HREC meeting the clock starts on receipt of a valid application and may stop while awaiting a satisfactory response from the applicant to a written request from the HREC for further information or clarification. For research requiring review at a full HREC meeting the clock starts on the relevant HREC meeting closing date and may stop while awaiting a satisfactory response from the applicant to a written request from the HREC for further information or clarification. |

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| SSA | <p>Site Specific Assessment Form: The mechanism used by a Queensland Health, health service facilities to document the level of support and suitability of a research project to be conducted at a site, whether that project is multi-centre or single-site.</p> |
| Substantial amendment | <p>A substantial (major) amendment is defined as an amendment to the terms of the HREC application, or to the protocol or any other supporting documentation, that is likely to affect to a significant degree:</p> <ul style="list-style-type: none"> • the safety or physical or mental integrity of the subjects of the trial • the scientific value of the trial • the conduct or management of the trial • the quality or safety of any investigational medicinal product used in the trial. <p>Substantial (major) amendments to the management of a study include:</p> <ul style="list-style-type: none"> • A change of sponsor(s) • Appointment of a new Principal Investigator • Extension of the research beyond the planned closing date for recruitment • The addition of new data collections to the study • The issue of an updated version of the Investigator's Brochure (IB) |
| 25 day clock | <p>The period of 25 days allowed for the SSA decision by the District CEO or delegate of a research application. The clock starts on receipt of a valid SSA and may stop while awaiting a satisfactory response from the applicant to a written request from the District/Site RGO for further information or clarification.</p> |
| Validation | <p>An administrative check carried out by an HREC Administrator to verify that an application is complete and accepted for review. Decisions on validation should be made within one week of receipt.</p> |
| Validation date | <p>For research not requiring review at a full HREC meeting the date on which a valid application is received by a HREC. For research requiring review at a full HREC meeting the relevant HREC meeting closing date</p> |

HOW TO APPLY

Before preparing your application, researchers should first consult the **Queensland Health Research Management Policy and Framework (RMP)** at http://www.health.qld.gov.au/ohmr/documents/res_man_pol_fram08.pdf. This policy outlines the Research Management Framework for the conduct of all research activities within or in association with Queensland Health. The policy requirements are consistent with the National Health and Medical Research Council (NHMRC) "National Statement on Ethical Conduct in Human Research" (2007) and the NHMRC and Universities Australia "Australian Code for the Responsible Conduct of Research" (2007) and relevant State legislation and regulations.

You may consider having a discussion with your local HREC Administration Office, HREC Chair or Research Governance Office/r prior to submission to clarify any local submission requirements.

Step 1 - Scientific and Ethical Review

Applicants must determine the most suitable HREC to submit for ethics review. Generally, the site at which potential participants will be recruited from will determine the location of the HREC. The contact details for QH HRECs may be found at: http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

For those sites that do not have a HREC, please refer to the 'Where do I submit my protocol?' at the Website to determine the responsible HREC. If you are unsure, contact the Research Ethics and Governance Unit on (07) 3234 0034.

In addition, applicants should be aware of the individual administrative requirements for each HREC. This includes:

- the number of ethics application copies required; and
- closing dates for ethics submissions and dates of HREC meetings;

These factors are important in planning and preparing your submissions for HREC review and site-specific assessment.

National Ethics Application Form (NEAF)

All applications (single site and multi centred) must be made on the Qld National Ethics Application Form (NEAF). (See p6 of the RUG for converting your NHMRC NEAF to the Qld NEAF)

What is the National Ethics Application Form (NEAF)?

The NEAF has been designed to meet the requirements of the NHMRC "National Statement on Ethical Conduct in Human Research" (2007). The National Statement asks the researcher to respond to the fundamental ethical principles and considerations for HRECs and researchers in determining the ethical acceptability of a research project. Please refer to it when you are preparing your NEAF application as it will answer any queries you have about what a HREC will be looking for from the responses you provide. The NEAF builds a customised ethics application form according to the type of research project by disabling questions and sections that are not relevant. You will only see questions relevant to your research proposal. It is important that all questions of the NEAF are completed correctly to allow the HREC to do a full ethics review.

Creating a NEAF application on the Qld Health NEAF site

The Queensland electronic NEAF application may be accessed on <http://www.ethicsform.org/au>. To access the Qld Health on-line forms you will first need to register online through the NEAF portal website. You only need to do this once and you can then fill in as many applications as you like.

Click '*Create a new form*'. Proceed with the preparation of your NEAF submission, systematically working through the screens, as you would normally. At the end of the completion of the NEAF (Section 11) you will automatically be taken to the Site Specific Assessment Form (SSA). Do not submit your SSA Form to the HREC administrator. The SSA Form is submitted to the RGO after HREC approval is granted.

Please note that when you print your QH NEAF it will indicate on the front of the form whether the application is complete. If it is not completed i.e. in draft form – **DO NOT SUBMIT** – complete the form.

Once your NEAF is complete, lock you form by clicking on '*Manage / lock the form*', '*Lock this HREC application*'. Submit your application to the relevant HREC.

Frequently asked questions regarding completing the online NEAF

Section 1. The HREC Application Reference Number on page 1 is optional – only insert this if you have been given an HREC reference number by the relevant HREC. Most HRECs will give you the HREC Ref number AFTER you have submitted your application.

Section 2.1. All projects MUST have a Chief researcher(s)/investigator(s) even if the project is a single centred study. For single centred studies the Chief Researcher and Principal Researcher / Investigator will be the same.

Section 2.4 The Contact Person is the person who will be the liaison person between the researcher team and the HREC / RGO. This is usually the clinical study coordinator.

Section 2 Entering researchers onto the NEAF. The easiest way is to go to "My Contacts" on the top of the NEAF page. Create a contact for each of the researchers associated with your project (include your own details). Then in the NEAF, when details of researchers are requested, you simply click on the icon (which looks like a letter box or a book with a bookmark) and this will take you to the Contact List. Select one person at a time from the list, click on "View" and check that the contact details are correct. Then click on "Copy Details into the Form". The contact details will upload into the form. The Contact List is attached to your account, not to the application, so the list can be used for all subsequent applications.

Section 6.1. All boxes must be answered either a), b) or c).

Section 10 For research where the researcher is not from a Qld Health institution eg a university, the Head of Department (HOD) is the HOD of the university department overseeing the researcher. Declaration b on the SSA Form is the declaration by the Department Head/s at the site where the research will be conducted.

Supporting documents

Any supporting documents to be submitted with the application (e.g. cover letter, participant information sheets, investigator brochure, protocol etc) should be electronically uploaded when completing the NEAF.

Click on '*Manage / lock the form*', '*Supporting documents*', '*Manage documents*' and then upload the relevant files from your computer. This ensures that the HREC receives all the supporting documentation.

Transferring a NEAF to another user

To transfer the NEAF to a collaborating researcher click on *'Manage / lock the form'*, *'Transfer This Application To Another User'*, type in the person's email address and click *'transfer to user'*. Do not lock the form before sending it to the local site investigator. In order to transfer the form to a recipient they must have an account on the Qld Health online form system.

To maintain version control:

- A NEAF may only be transferred to one user at a time.
- After completing the relevant sections of the NEAF the collaborating researcher **MUST** transfer the NEAF back to the originator of the form for it to be 'locked'.
- Only the originator of a NEAF can 'lock' the NEAF (however a collaborating researcher can 'lock' a SSA form).

What happens when a NEAF is transferred?

The recipient (collaborating researcher) will receive an automated email notifying them that the form has been transferred to their account and that they must log-on to the Online Forms website to access the form. When a person receives this notification from the coordinating investigator they will be able to view and change the NEAF,

Retrieving a NEAF

For the originator of a NEAF to retrieve a NEAF that has been transferred, follow the same process as above. The *'Enter email address'* box will have been replaced by a *'Retrieve Application'* button. Click this button and the form will be returned to you.

What to do with NEAF applications created on the NHMRC NEAF portal

If you have created a NEAF on the NHMRC NEAF portal (as opposed to the Qld online NEAF portal) you will need to import this as an .xml file into the Qld NEAF portal in order to complete your application. To do this you will need to save your NHMRC NEAF application as an xml file.

Saving the NHMRC NEAF as an .xml file

When you have the particular proposal open on the NHMRC NEAF web site, click the **Save to Disk** button at the top right of screen. In the pop-up box that appears, select XML from the list and this will allow you to save in XML format. You can save this file where you need to on your computer (just like a PDF). **Do not open the .xml file** at any stage – opening the .xml file will corrupt the document and you will not be able to import it.

Once you have saved your NHMRC NEAF application onto your computer as an .xml file click on the *'Forms'* page on the Qld NEAF and then click on *'Import (NHMRC) XML Form'* to import your NHMRC NEAF into the Qld NEAF portal. You can then complete your application as per usual.

Moving the NEAF to another category

When you have finished with your NEAF you can move it to another category. Users can create different categories e.g. obsolete, archived etc. Click on *'Move to another category'*. On the category page you can now create different categories to store your NEAF by clicking on the *'Add category'* button. Select the forms you wish to move and then move the selected forms to the appropriate category.

What happens next with the HREC Application?

On receipt of the hard copies of the application, the HREC Co-ordinator will check to see whether the application is valid. This is a simple administrative check to determine that the application is complete and has all the relevant supporting documentation. Researchers are encouraged to consult the “**HREC Submission Checklist for Researchers**” prior to submission to ensure their application is valid.

A standard letter/email acknowledging receipt of a valid research application will be sent from the HREC Co-ordinator. The letter will include a **HREC reference number** and the meeting date at which the project will be reviewed. The **HREC reference number must be cited on all future correspondence** with the HREC for ease of reference. All the information from your application will then be automatically entered into the Research Ethics Database (AU-RED).

What is the Australian – Research Ethics Database (AU-RED)?

AU-RED is a secure web-based Research Ethics Database that allows researchers to complete and submit a NEAF application online. All details on your NEAF submission will be electronically downloaded into the Research Ethics Database (AU-RED). This data including your personal information is stored in the AU-RED application in the United Kingdom and protected by British privacy legislation– the *Data Protection Act 1998 (UK)*. Confidential personal information that is stored by Queensland Health is protected by the Department’s Information Standard 42A (Privacy).

Subject to the HREC meeting frequency, a final decision about the ethical acceptability of a research proposal will be made within approximately 60 calendar days. In some cases, the research application will undergo a process of scientific review prior to HREC consideration. This involves review by either a scientific sub-committee or a panel of one or more independent expert scientific reviewers. The review clock stops and starts when information is requested and information is received. Therefore a review time of 60 calendar days or less requires both the HREC and the researcher to deal with requests and information in a timely manner.

You may monitor the progress of your application to an HREC by logging in to your user account at www.ethicsform.org/au and clicking on the ‘*Manage/Lock HREC Form*’ link on the Forms page and clicking on the ‘*See the progress of your application*’ link located in the top left hand corner of the Manage HREC Application screen. For more information or assistance please visit the website’s Help page.

For industry sponsored research, independent scientific review may be required for first in human protocols and possibly other phase studies. At times an independent review will be used to inform the decision of the Committee. The cost of independent review will be invoiced to the sponsor at cost recovery.

At the HREC meeting, the Committee may decide to seek clarification on specific issues before it makes its decision. This will be in the form of a written request for clarification or further information and/or the applicant may be invited to attend the meeting to discuss the proposal. This offer is at the Committee’s discretion. It is the applicant’s responsibility to provide a prompt written response to the Committee’s request. It is important to remember that the time taken to respond will impact on the overall amount of time in which a final committee decision will be made. Requests for clarification or further information may also be made to the applicant for response prior to HREC review or forwarded directly to the HREC for further consideration at the time of the meeting.

If the response received is not satisfactory then the Committee may give an unfavourable opinion or it may decide if the majority of concerns were answered satisfactorily to let the applicants have a further opportunity to respond to any outstanding questions.

The final decision of a HREC will be to either “Grant Approval” or “Reject” the research proposal.

Approval is contingent on certain conditions and reporting requirements to ensure the research is conducted in an ethical manner. The approval letter will list these conditions. **A HREC “Approval” is not authorisation to commence research. Authorisation to commence the research is granted by the QH District CEO or delegate.**

If the research proposal is rejected the HREC will give justifications based on the principles in the NHMRC “*National Statement on Ethical Conduct in Human Research*” (2007).

Step 2 - Research Governance Review

Site Specific Assessment Form (SSA Form)

What is a Site-Specific Assessment (SSA) Form?

An SSA form documents all aspects of research governance arrangements for a project at a particular Queensland Health site. The assessment considers the following matters:

- Adequate resources (financial, human, equipment and infrastructure) for the research to proceed at the site and identified as appropriate, accountable and available;
- Researchers have the necessary expertise and experience; if not, relevant training is planned before carrying out their role in the research project
- Compliance with relevant laws, policies and codes of conduct relating to matters such as privacy, confidentiality, consent, bio-safety, professional standards, and radiation safety

A separate SSA Form must be completed for each project and for each site at which the project is to be conducted.

At each site where it is proposed to undertake the research project, the Principal Investigator must complete a Site Specific Assessment (SSA) Form for every project. The SSA is a component of research governance and is separate from the ethical review made by a HREC.

The SSA process deals primarily with research budgets, funding sources, recruitment, human resources, contracts/agreements and local site policies and will require approval prior to undertaking the research. Importantly – the **Actual Monetary** and **In Kind** costs for the research project are to be documented in the budget section of the SSA. **Failure to do so may prevent authorisation of the research at the nominated site.**

Applicants should begin negotiations with relevant QH personnel responsible for resources that will be required for the project as early as possible prior to the final HREC approval.

To create a SSA Form

At the end of your NEAF application you will automatically be taken to a new form which will ask 'Please select whether you want to raise a SSA or PHA form'. Click on the appropriate box and complete the form.

The SSA form will be partially electronically populated on line with information from your NEAF. You will be required to complete those areas of the SSA that relate to your project once your study has been approved. Examples on how to fill out a SSA can be found on the Queensland Research Ethics and Governance Unit website http://www.health.qld.gov.au/ohmr/documents/ssa_full_suite_docs.pdf. The SSA form is only completed once all application sections have been finalised and HREC approval is received.

Where there is Actual Monetary and In Kind costs that may have an impact of the District budget, the District Finance Manager or delegate must sign off on the SSA.

Entering researchers onto the SSA Form

The easiest way is to go to "My Contacts" on the top of the NEAF page. Create a contact for each of the researchers associated with your project (include your own details). Then in the SSA Form, when details of researchers are requested, you simply click on the icon (which looks like a letter box or a book with a bookmark) and

this will take you to the Contact List. Select one person at a time from the list, click on "View" and check that the contact details are correct. Then click on "Copy Details into the Form". The contact details will upload into the form. The Contact List is attached to your account, not to the application, so the list can be used for all subsequent applications.

Supporting documents

Any supporting documents to be submitted with the application (e.g. CTN, CTA, investigator brochure, protocol, HREC approval letter etc) should be electronically uploaded at this time.

Click on '*Manage / lock the form*', '*Supporting documents*', '*Manage documents*' and then upload the relevant files from your computer. This ensures that the RGO receives all the supporting documentation.

SSA forms – multi centred research

The co-ordinating investigator should create a Site Specific Assessment Form for each site where the research will take place and transfer the form to the local Principal Investigator at each site to complete.

To transfer a form to a collaborator, the collaborator must first register as a user of the Online Forms website.

Transferring a SSA form

Click on the '*Forms*' page and locate the application you wish to transfer to another user. Click on the '*Manage/ Lock this SSA*' link. You are now on the '*Manage SSA*' form page. Go to the '*Transfer Ownership of This SSA Form to Another User*' section. Enter the email address of the person you wish to transfer the form to in the indicated box. The collaborator will receive an automated email notifying them that the form has been transferred to their account and that they must log-on to the Online Forms website to access the form.

Do not lock the form before sending it to the local site investigator.

To maintain version control, a form may only be transferred to one user at a time.

Retrieving a SSA form

To retrieve a form that has been transferred, follow the same process as above. The '*Enter email address*' box will have been replaced by a '*Retrieve Application*' button. Click this button and the form will be returned to you.

What happens when a SSA form is transferred?

The transferee will receive an email from the transferor notifying them when they are able to access and complete the Site Specific Assessment form. To access the form, you must be registered as an Online forms website user. When a person receives notification from the coordinating investigator they will be able to view, change, lock and print the SSA form and then submit the form to their local RGO.

What happens next with my SSA Application?

The completed SSA is submitted to the site Research Governance Office/r or in some instances to the HREC office where the District does not have a governance structure. This is likely to change as these systems mature and as information becomes available – research governance contact details will become available on the REGU website.

What is the Research Governance Office/function?

The Research Governance Office/function is responsible for assessing site-specific aspects of research applications, making a recommendation to the Health Service District Manager/delegate as to whether a research project should be authorised at that site, and overseeing that authorised research at the site meets the appropriate standards.

The Research Governance Office/r will provide a recommendation to the District CEO or delegate for authorisation to conduct research at the nominated site. A letter of authorisation to conduct research will be issued to the applicant usually within 25 calendar days from submission. The District CEO or delegate retains responsibility for authorising the conduct of research at the site.

Commencement of the research can only occur once District authorisation has been provided. HREC approval alone is not authorisation to conduct the research.

Access to Confidential Health Information for the Purposes of Research

If the research proposal involves access to and use of confidential health information for the purposes of research, an application to the Queensland Health Director-General or delegate to access the information under the provisions of the *Public Health Act 2005 (Qld)* s281 is required. For further information about how to make application to access confidential information for the purposes of research visit the following website: http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

Research Involving Adults with Impaired Capacity to consent

If the research proposal involves participants who may be, by reason of physical and mental incapacity, incapable of giving informed consent to participate in the research, approval from the Guardianship and Administration Tribunal (GAAT) is required. Where a person is over the legal age of consent but is unable to give consent, a written application to GAAT must be submitted after HREC approval is gained. GAAT can be contacted on:

Guardianship and Administration Tribunal
16th Floor
80 Albert Street
GPO Box 1639
Telephone: 07 3239 6027
Facsimile: 07 3221 9156
<http://www.gaat.qld.gov.au/>

[http://www.gaat.qld.gov.au/files/Application for Approval to Conduct Clinical Research.doc](http://www.gaat.qld.gov.au/files/Application%20for%20Approval%20to%20Conduct%20Clinical%20Research.doc)

Multi-Centre Research Applications

In 2009 Queensland Health will adopt state-wide mutual acceptance for scientific and ethics review. Mutual acceptance works to streamline review processes for research that involves more than one Queensland Health site, by ensuring only a single scientific and ethics review of a research protocol. This process is aimed at reducing the duplications of HREC reviews. Details on how to make application for single review for multi-centre research will be become available in late 2009.

Currently, a HREC may approve a study, without further ethical review, which another institutional ethics committee has approved and the project/protocol appears to conform to the requirements of the Committee. The HREC reserves the right to ratify the previous decision, request amendments or clarification or reject the protocol. As a formal single ethical review process for Queensland has not yet been introduced a HREC may still require a full ethical review of a project despite a previous HREC approval from another institution.

Low or Negligible Risk Research exempt from full ethical review

How can research that is 'low risk' be ethically reviewed?

Section 5.1.6 – 5.1.8 of the NHMRC "National Statement on Ethical Conduct in Human Research" (2007) outlines processes for ethical review for research involving more than low risk, low risk research and negligible risk research. QH Institutions may elect to adopt processes to conduct ethical review of 'low and negligible risk' research.

In some circumstances, a research proposal may be '*Low Risk*' or '*Negligible Risk*' and may be suitable to be exempt from full ethics review. If you believe this may be the case, refer to the "[Advice regarding negligible and low risk ethical review processes](#)" and complete the "[Checklist for Research that is Exempt from full HREC review](#)" http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp. Researchers are encouraged to contact the local HREC office / RGO to gain an independent assessment of whether the project satisfies the criteria for alternate review rather than that of a full HREC before proceeding with their application.

Research which qualifies for negligible and low risk research review

- Complete the "Checklist for Research that is Exempt from full HREC review" http://www.health.qld.gov.au/ohmr/documents/low_risk_app.doc
- Complete the "Application for Ethical Review of Negligible or Low Risk Research" http://www.health.qld.gov.au/ohmr/documents/low_risk_app.doc
- Submit the completed 'Checklist for Research that is Exempt from full HREC review' and the 'Application for Ethical Review of Negligible or Low Risk Research' to the institution's low and negligible risk research review panel.

See Flow Chart 1: 'Queensland Health Processes for Low and Negligible Risk Ethical Review'

Exceptional circumstances exempt from full ethical review

In exceptional circumstances, where as a matter of public policy, and in the national interest, it is essential that an application should be reviewed urgently to allow a health-related research study to commence as quickly as possible. Such circumstances could include the urgent need for research data in a field that is currently the subject of major public anxiety, or where there is an urgent threat to public health. There could also be a need to capitalise on a unique opportunity for significant research that is likely to prove temporary.

The District CEO or Delegate may grant approval under exceptional circumstances for a project/protocol where:

- Another institutional ethics committee has approved the project/protocol and the project/protocol appears to conform to the requirements of the Committee. Refer to sections on multi-centre review (National Statement, Chapter 5.3)
- Clinical need necessitates urgent approval of the protocol.

Note that ethical review under exceptional circumstances is never justifiable solely on the grounds of a researcher's claim to the need for urgent review of their project based on failure to meet deadlines. The onus is on the researchers to ensure the timely submission of their proposal to the HREC and completion of site-specific requirements.

Applications submitted for review under exceptional circumstances should contain:

- Completed NEAF or original submission if not on NEAF and time factor does not allow time for NEAF to be completed;
- Evidence of HREC approval;
- Study protocol;
- A request for exceptional circumstances review in writing and containing the reason for requesting review under exceptional circumstances and justification for the request by aligning the protocol with the above categories

The District CEO / delegate reserves the right to ratify the previous decision, request amendments or clarification or reject the protocol.

Quality Assurance Activities

For Quality Assurance activities (including types of audits or quality assurance) as guided by the NHMRC "When does Quality Assurance in Healthcare Require Independent Ethics Review":

http://www.nhmrc.gov.au/health_ethics/human/conduct/guidelines/ files/e46.pdf

- Seek advice from your local HREC office / RGO
- Submit to a local QA Committee
- For further information on Quality Assurance Committees please refer to the Clinical Practice Improvement Centre website:
http://www.health.qld.gov.au/cpic/quality_strategy/quality_assur_com.asp.

Amendments to Research post-Authorisation

Amendments are changes made to the research after local Authorisation has been granted. There are four types of amendments:

- Amendments to the research project which may affect the ongoing ethical acceptability of the project;
- Amendments to the Research Project which may affect the ongoing site acceptability of the Project ;
- Amendments to the Research Project which may affect both the ethical acceptability and site acceptability of the project or;
- Minor amendments to the Research Project which do not affect either the ethical acceptability or site acceptability of the project (e.g. typographical errors, addition to study team).

Amendments to the research project which may affect the ongoing ethical acceptability of the project

These are amendments that, as a condition of HREC approval, the site investigator is required to submit a request for approval of the proposed amendment to the HREC. Amendments that require approval by a HREC include changes to the following:

- The safety, physical and/or mental integrity of the participants in the trial;
- The scientific value of the trial;
- The quality or safety of any investigational medicinal product used in the trial.

Amendments which may affect the ongoing ethical acceptability of a project are considered major amendments and should be reflected in a revised online NEAF (the locked NEAF will need to be duplicated before you can revise the document – go to “*Manage/Lock HREC Form*” and select ‘*Duplicate application*’ (accompanied by a cover letter from the principal investigator, stating the changes and reasons for the changes, and all relevant updated documents). Hard copies of the revised NEAF, the cover letter and all relevant updated documents (with tracked changes) must also be submitted to the HREC coordinator as per standard HREC SOP. The NEAF does not have a ‘*track changes*’ function.

The HREC may require further clarification or information regarding the amendment prior to granting approval. The applicant should respond to these queries promptly in writing. The amendment can be implemented once HREC approval is granted. The outcome of the HREC review and any revised documentation pertaining to the research project must also be submitted by the site Principal Investigator to the relevant site RGO for the Health Service Districts record.

Amendments to the Research Project which may affect the ongoing site acceptability of the Project

These are amendments which only impact upon the suitability of the research to be conducted at a particular site. Amendment requests for an authorised research project may be submitted directly to the Research Governance Office/r (by-passing the HREC) **only** when the amendment requires:

- No change to the authorised NEAF; **and**
- A change to **one or more** of the following sections of the QH SSA form (which relate to the specific site **only**):
 - Section 4 – Training
 - Section 6 – Anticipated start and finish dates
 - Section 8a(ii), b(ii), c(ii) – Medicines Australia Standard Indemnity Form(s)
 - Section 8a(iii), b(iii), c(iii) – Evidence of adequate insurance cover
 - Section 8d – Medicines Australia Standard Clinical Trial Agreement(s)
 - Section 11 – Departments and services involved in the research
 - Section 13 – QH account number(s) / cost centre details
 - Section 14 – Finance authorisation
 - Section 13 (a-f) – Declarations and authorisations.

Amendments which may affect the ongoing site acceptability of a project should be reflected in a revised online SSA form (accompanied by a cover letter from the principal investigator, stating the changes and reasons for changes, and all relevant updated documents). Hard copies of the SSA form, the cover letter and all relevant updated documents with tracked changes must also be submitted to the RGO as per standard RGO SOP.

Upon receipt of the written request for a site amendment, the RGO will determine whether authorisation from the District CEO or delegate is required or if RGO approval only is necessary. The RGO will notify the site Principal Investigator as to whether or not authorisation has been granted for the amendment to be implemented at the site.

The site investigator may commence the amendment at the site only once notification of amendment authorisation has been received.

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|--|
| <p>Amendments to the Research Project which may affect both the ethical acceptability and site acceptability of the project</p> |
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Where a proposed amendment to the research project may affect both the ethical acceptability and site suitability of the project, the site Principal Investigator must submit an amendment request to both the HREC and RGO. Amendments which may affect both the ethical acceptability and site acceptability of the project are considered major amendments and should be reflected in a revised online NEAF application (the locked NEAF will need to be duplicated before you can revise the document – go to “*Manage/Lock HREC Form*” and select ‘*Duplicate application*’) and a revised online SSA form (accompanied by a cover letter from the principal investigator, stating the changes and reasons for changes, and all relevant updated documents). Hard copies of the NEAF, the cover letter and all relevant updated documents (with track changes) must also be submitted to the HREC coordinator. The NEAF does not have a ‘*track changes*’ function.

The HREC will review the amendment request according to standard procedures and will notify the site investigator in writing of its decision. Once HREC approval has been given for the amendments hard copies of the HREC approval letter, revised SSA form, the cover letter and all relevant updated documents with track changes must be submitted to the RGO for authorisation to implement the amendment at the site.

The amendment cannot proceed until site authorisation is granted.

Minor amendments to the Research Project which do not affect either the ethical acceptability or site acceptability of the project (e.g. typographical errors, additions to the study team)

Amendments which do not affect either the ethical acceptability or site acceptability of the project should be submitted in hard copy to the HREC coordinator. These should include a cover letter from the principal investigator, stating the changes and reasons for changes, and all relevant updated documents with tracked changes.

What if the amendment is for urgent safety measures?

Where it is necessary to eliminate an immediate hazard to the research participants, amendments to the research project may be implemented without prior HREC review and authorisation from the District Manager/delegate (if necessary). As soon as possible, the implemented amendment should be submitted to the HREC and/or RGO as above

All site investigators are encouraged to contact the local HREC Co-ordinator or RGO to discuss the amendment. Alternatively, the RGO liaises with the HREC Co-ordinator and if it is considered that an amendment needs review by both the HREC and RGO, you will be contacted to provide additional documentation if required

Fees for HREC Review and Site-Specific Assessment:

For fully sponsored industry trials, a fee for ethics review and site-specific assessment is charged. First in Human and in some situations early Phase trials may require an independent expert review and a fee may be applicable. The charges are reviewed on an annual basis, commencing 3 November 2008. Fees for review of commercially sponsored research by HRECs and Governance Review (site-specific assessments) can be accessed at:

http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

Monitoring Requirements for Approved Research

Each institution has ultimate responsibility for ensuring, via its research governance arrangements, that all its approved research is monitored (*National Statement Section 5.5.1*). Researchers should follow the NHMRC AHEC position statement: Monitoring and reporting of safety for clinical trials involving therapeutic products: http://www.nhmrc.gov.au/health_ethics/hrecs/reference/files/090609_nhmrc_position_statement.pdf

Mechanisms for monitoring can include:

- a. reports from researchers;
- b. reports from independent agencies (such as a data and safety monitoring board);
- c. review of adverse event reports;
- d. random inspections of research sites, data, or consent documentation; and
- e. interviews with research participants or other forms of feedback from them.

As a condition of ethics approval, researchers must comply with all reporting requirements stipulated in the HREC approval letter and/or Letter of authorisation to conduct research. Reporting requirements include:

Progress reports: These are required at regular intervals (as stipulated by the HREC) and document the development of the research project and its compliance with ethical standards. Progress Report forms can be accessed at:
http://www.health.qld.gov.au/ohmr/html/requ/requ_home.asp

Final Reports: A report to document the completion of the project. Final reports should include the final study report or any publications that have arisen from the research findings. Final Reports can be accessed at:
http://www.health.qld.gov.au/ohmr/html/requ/requ_home.asp

Adverse Event Reporting: It is the responsibility of researchers, HRECs, and the institution they advise, to protect the safety of participants in clinical trials. In order to effectively undertake this responsibility, HRECs need to receive sufficient reliable information about the implications of adverse events or reactions.

Data Safety Monitoring Board Reports. Institutions responsible for the conduct of clinical research should require that for a large multi-centre trial, a Data and Safety Monitoring Board (DSMB) is used and there is a mechanism for informing the HREC of any relevant emerging data from the DSMB

Queensland Health's requirements for reporting of Serious Adverse Events

On site SAE's should be reported to the HREC and RGO within 24hours of the occurrence or within 24hours of the principal investigator becoming aware of the incident.

Safety reporting including the reporting of SAEs, SUSARs etc should follow the NHMRC AHEC position statement:
http://www.nhmrc.gov.au/health_ethics/hreecs/reference/files/090609_nhmrc_position_statement.pdf

Adverse Event report forms can be accessed at:
http://www.health.qld.gov.au/ohmr/html/requ/requ_home.asp

Suspension of Approved Research

A HREC may consider it appropriate that the adverse event/s and/or monitoring reports requires the immediate suspension or discontinuation of the ethical approval of the research project or where the QH District CEO or delegate is satisfied that circumstances have arisen such that it is no longer appropriate to conduct a research project at the HSD site.

In both circumstances the researcher will be advised of the decision to suspend or withdraw the research as soon as possible. The researcher cannot continue with the research if either the HREC or District CEO or delegate has suspended or withdrawn authorisation.

Complaints

An Institution may receive complaints about the researchers, or the conduct of research, or conduct of a Human Research Ethics Committee (HREC) or any other related ethical review body.

See Flow Chart 2: Queensland Health Complaints Process – HRECs and Research Misconduct

Complaints about the decision to ethically approve or authorise a research project:

Researchers may appeal a decision of either the HREC and/or the outcome of a site-specific assessment. HREC appeals will be dealt with according to the Queensland Health Complaints process for HRECs (above).

An appeal relating to the outcome of a site-specific assessment will be dealt with by the District CEO or delegate at the HSD.

Complaints about the Researcher and/ or the conduct of an authorised research project:

All concerns, allegations or complaints must be reported to the HREC and/or the RGO in the first instance. The HREC and RGO will then determine whether the matter should be dealt with by the RGO alone or handled by both the HREC and RGO.

Where the concern or allegation relates to researcher misconduct, the complaint handling must involve the RGO. The matter should be dealt with in accordance with the NHMRC and Universities Australia “Australian Code for the Responsible Conduct of Research” (2007) and the QH Complaints Process – Research Misconduct.

A number of people within a QH HSD have responsibility for investigating and resolving allegations of research misconduct, such as, District CEO/delegate, Head of Departments, research supervisors and researchers.

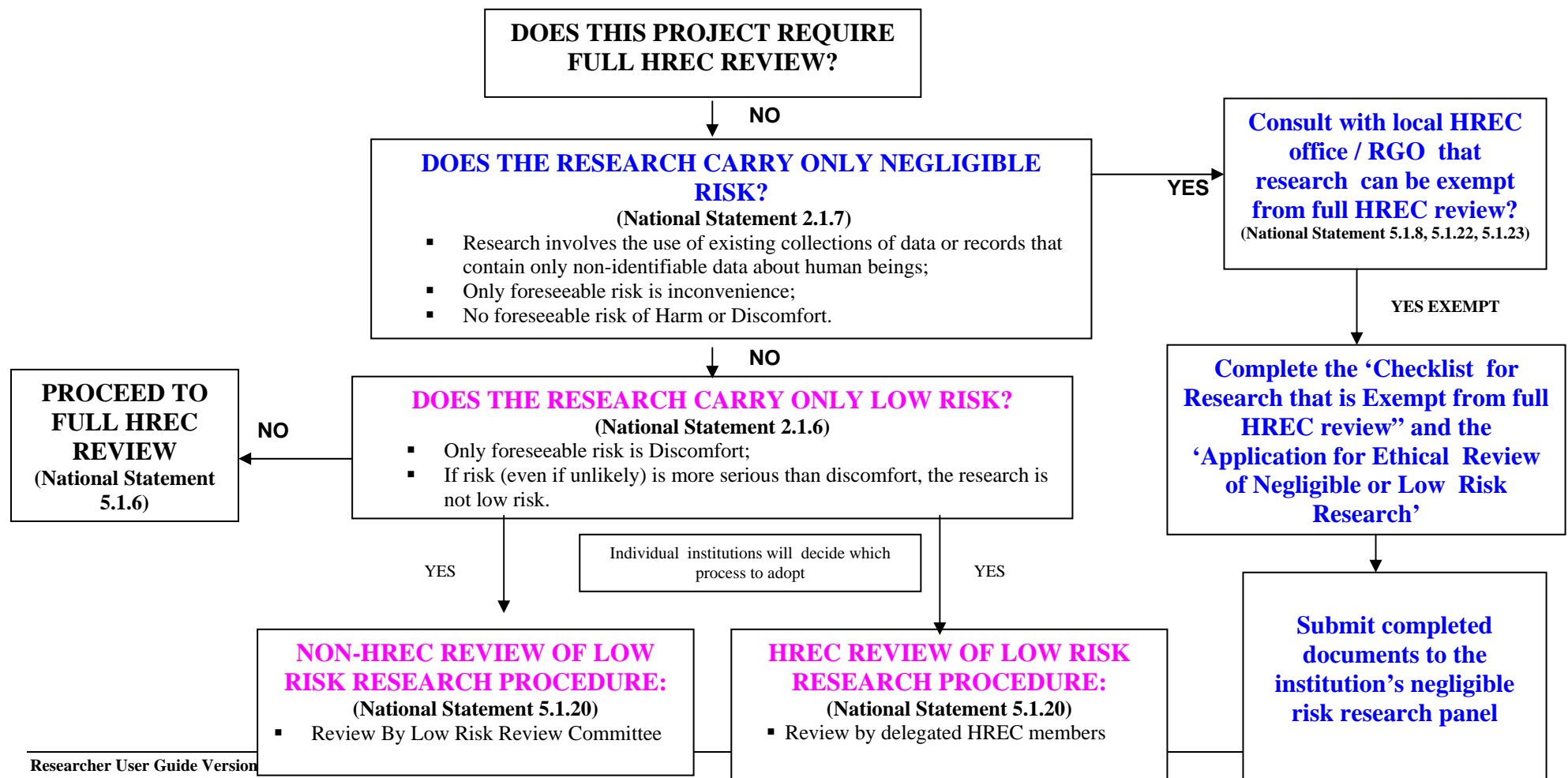
I am a researcher and have been notified that a research complaint has been made against me. Will I be given a chance to fairly participate in resolving the issue?

Yes, all parties to a research complaint should be given fair participation and natural justice in resolving research complaints. For further information, see section 12 “The Framework for Resolving Allegations” in the NHMRC and Universities Australia “Australian Code for the Responsible Conduct of Research” (2007). QH has “General Principles of Handling Research Complaints” that is consistent with this guideline.

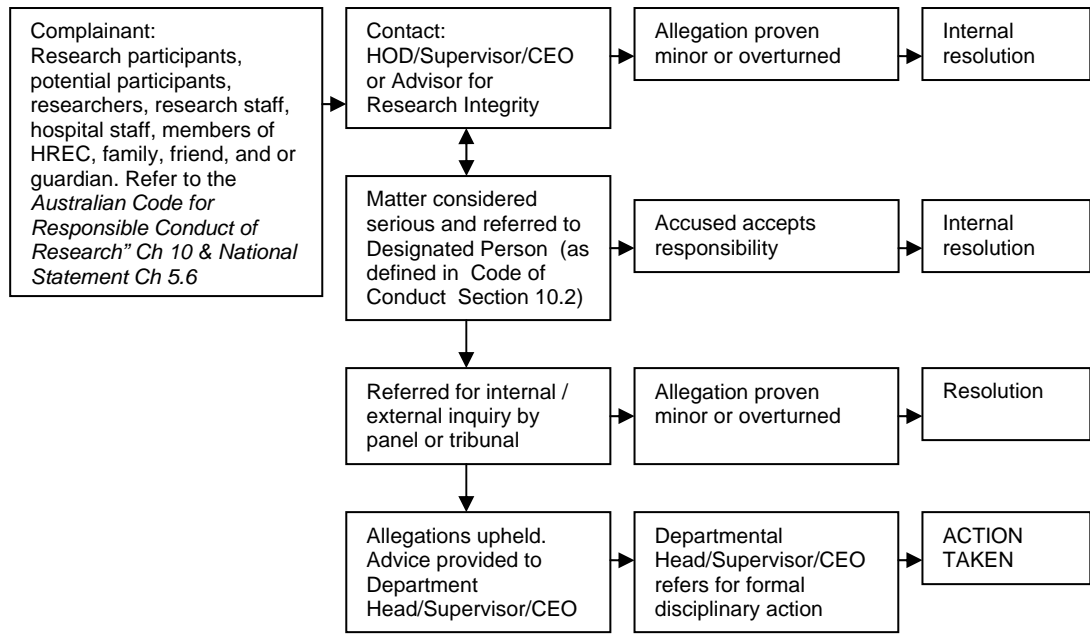
See Flow Chart 3: Pathway for management of complaints about the conduct of a Human Research Ethics Committee (HREC) or any other related ethical review body.

Flow Chart 1 – Queensland Health Processes for Low and Negligible Risk Ethical Review

PROCESSES FOR LOW AND NEGLIGIBLE RISK ETHICAL REVIEW



Flow Chart 2: Pathway for management of complaints about the researcher or conduct of the research



See Flow Chart 3: Pathway for management of complaints about the conduct of a Human Research Ethics Committee (HREC) or any other related ethical review body

