



Researcher User Guide (RUG)

Office of Health and Medical Research

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QUEENSLAND HEALTH RESEARCHER USER GUIDE (RUG)

INTRODUCTION

This user guide provides information for researchers on how to obtain authorisation to commence a research study 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 ethical 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 study to be conducted and completed at a site, whether that study 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 study governance arrangements and will assist the District CEO or delegate decision on granting authorisation to conduct the research at the site. Research cannot be commenced at a site until the Governance Authorisation has been granted.

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

All researchers conducting studies within QH and/or using QH resources should manage the research in accordance with this RUG, with effect from 1 July 2010.

DEFINITIONS AND APPREVIATIONS

AuRED	A secure web-based Research Ethics Database that allows researchers to complete and submit a NEAF application online.
Central Coordinating Service (CCS)	The Central Coordinating Service (CCS) provides a “one stop shop” information service for the processing of multi-centre research applications within Queensland Health sites. Use of the Central Coordinating Service for multi-centre research in Qld Health sites is mandatory from 1 July 2010.
Coordinating Principal Researcher	The investigator responsible for coordinating a research study. For single centred studies the terms “Coordinating Principal Investigator”, “Coordinating Principal Researcher”, “site Principal Investigator” and “Principal Investigator” are all synonymous.
Clinical Research Coordinator	The person designated by the Principal Investigator (PI) to be responsible for liaising with the HREC / research governance office(r). May also be known as the site coordinator, contact person, study liaison officer.
Contact person	The person designated by the PI to be responsible for liaising with the HREC / research governance office(r). May also be known as the site coordinator, clinical research coordinator, study liaison officer.
CPI	Coordinating Principal Investigator. The investigator responsible for coordinating a multi-centre research study, 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”, “Coordinating Principal Researcher”, “site Principal Investigator” and “Principal Investigator” are all synonymous.
HREC Coordinator	An employee of the institution who provides administrative support and advice on the institution’s process of ethics review of research studies. 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	<p>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:</p> <ul style="list-style-type: none">• Correction of typographical errors in the protocol or other study documentation• Amended contact details for the sponsor or study staff• Appointment of new support staff
MCR	<p>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.</p> <p>For MCR which is to be submitted to the CCS the research project will include sites which cross ethical jurisdictions, and would have been reviewed previously by more than one HREC.</p>
Negligible risk research	<p>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."</p>
Principal Investigator	<p>An investigator who acts as Principal Investigator at a study site i.e. the investigator responsible for the overall conduct of the research study at an individual site within a Health Service District of QH. For single centred studies the terms "Coordinating Principal Investigator", "Coordinating Principal Researcher", "site Principal Investigator" and "Principal Investigator" are all synonymous.</p>
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> <ol 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.

REGU	Research Ethics and Governance Unit.
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 an institution / district 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 study 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 study i.e. the investigator responsible for the overall conduct of the research study at an individual site within a Health Service District of QH. For single centred studies the terms “Coordinating Principal Investigator”, “Coordinating Principal Researcher”, “Site Principal Investigator” and “Principal Investigator” are all synonymous.
Site-specific Amendment	An amendment request for an authorised research study that may be submitted by the applicant to the site/District Research Governance Office/r only (by-passing 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 research coordinator”, “site coordinator” and “study 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. For research requiring review at a full HREC meeting the clock starts on the relevant HREC meeting closing date.

SSA	<p>Site Specific Assessment</p> <p>The mechanism used by health service facilities within Queensland Health, to document the level of support and suitability of a research study to be conducted at a site, whether that study is multi-centre or single-site.</p>
Stop Clock facility	<p>For HREC applications, the time when the 60 day clock is stopped while awaiting a satisfactory response from the applicant to a written request from the HREC for further information or clarification.</p> <p>For SSA applications, the time when the 25 day clock is stopped while awaiting a satisfactory response from the applicant to a written request from the District/Site RGO for further information or clarification.</p>
Study liaison officer	<p>The person designated by the PI to be responsible for liaising with the HREC / District/site research governance personnel. The terms “contact person”, “clinical research coordinator”, “site coordinator” and “study liaison officer” are all synonymous.</p>
Substantial amendment	<p>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.
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.</p>
Validation	<p>An administrative check carried out by an HREC or RGO 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.</p> <p>For research requiring review at a full HREC meeting, the relevant HREC meeting closing date</p> <p>For research governance: the date on which a valid application is received by a RGO.</p>

HOW TO APPLY

Before preparing your application, researchers should first consult the **Queensland Health Research Management Policy (RMP)** at http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp. 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 also consider having a discussion with the reviewing HREC Administration Office or local site / district Research Governance Office/r prior to submission to clarify any local submission requirements.

Single Site Studies

If undertaking a single site study, applicants must determine the most suitable HREC for submission for ethical review. The QH REGU webpage: http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp lists all QH HRECs and their meeting dates. Generally, the site at which potential participants will be recruited from will determine the location of the reviewing HREC.

For those sites that do not have an HREC, please refer to the '*Where do I submit my protocol?*' on the REGU Website ("Information for Researchers" section) 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

Information about these individual requirements is found on the REGU webpage.

Multi-centre Studies

A Coordinating Principal Investigator (CPI) must be nominated for all multi-centre research studies. The Coordinating Principal Investigator must be employed and professionally based in an Australian organisation. For international studies with a Coordinating Principal Investigator outside Australia, a health professional based in Australia must be nominated as the Coordinating Principal Investigator responsible for the conduct of the research in Australia.

The Coordinating Principal Investigator/or delegate will be responsible for correspondence relating to the ethical review and the HREC in accordance with the *National Statement on Ethical Conduct in Human Research (2007)*, Chapter 5.2. This function, in part, may be delegated to a person who will act as a contact person on behalf of the Coordinating Principal Investigator.

The Coordinating Principal Investigator must contact the Central Coordinating Service (CSS) to enable allocation of the study to the appropriate reviewing HREC. The allocation of the study to the reviewing HREC is the decision of the CCS, in consultation with the CPI. This service will also provide advice on supporting documentation requirements.

If contemplating undertaking multi-centre research, you should contact the Central Coordinating Service (CSS) at QH REGU on 07 323 40654 or via email QHCCS@health.qld.gov.au or REGU@health.qld.gov.au.

1. Scientific and Ethical Review

1.1 National Ethics Application Form (NEAF)

All applications submitted to a QH HREC for review and approval (single site and multi-centre) must be made on the online Infonetica 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 study.

Refer to the National Statement 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 study 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 undertake a full ethics review.

Use the  button on the online NEAF application for guidance on how to complete the NEAF.

1.1.1 Creating a NEAF application on the online Infonetica NEAF site

All Studies

To access the Infonetica online NEAF, you will first need to register online through the ‘ethicsform’ portal website. To register, go to: <https://ethicsform.org/au/Users/CreateAccount.aspx>. You only need to register once.

The Infonetica electronic NEAF may be accessed on <http://ethicsform.org/au>.

Click ‘*Create new project*’. Proceed with the preparation of your NEAF submission, systematically working through the screens.

Please note that if you print your Infonetica NEAF before you have generated a submission code, it will indicate on the front of the form that it is incomplete and the word “Draft” will be watermarked on the pages. **DO NOT SUBMIT** – complete the form and generate a submission code by clicking on ‘*Manage*’ then ‘*Submission*’, ‘*Generate submission code*’. The submission code will be printed on the lower right hand side of each page. Then proceed as indicated below, depending on the type of study.

For further information please see Section ‘*Creating a new project*’ in the User Manual:

<https://ethicsform.org/Au/Help/AU%20Online%20Forms%20for%20Research%20User%20Manual%20v1.pdf>

Negotiations pertaining to the research governance processes (District & Legislative requirements as documented on the SSA Form) should commence and run parallel to the HREC approval cycle. Do not submit your SSA Form to the HREC administrator. The SSA Form is submitted to the RGO **after** HREC approval is granted.

Note: The NEAF on the NHMRC website and the NEAF on the Infonetica online forms website ask identical questions. The only difference is the order in which the questions are asked.

Once your NEAF is completed, generate a submission code for your form by clicking on 'Manage' then 'Submission', 'Generate submission code'. Prior to submission, upload all supporting documentation onto the online forms website against the application. For details on uploading supporting documents, see Section "Uploading Supporting Documents" or Section 'The Documents tab' in the User Manual:

<https://ethicsform.org/Au/Help/AU%20Online%20Forms%20for%20Research%20User%20Manual%20v1.pdf>

For further information please see Section 'The submission tab' in the User Manual:

<https://ethicsform.org/Au/Help/AU%20Online%20Forms%20for%20Research%20User%20Manual%20v1.pdf>

1.1.2 Uploading 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 'My projects' 'Existing projects'. On the relevant application click on 'Manage', 'Documents' and then 'Upload' and then upload the relevant files from your computer. This ensures that the HREC receives all the supporting documentation. Note: Supporting documents can still be uploaded even after the NEAF application has been submitted to the HREC.

For further information please see Section 'The Documents tab' in the User Manual:

<https://ethicsform.org/Au/Help/AU%20Online%20Forms%20for%20Research%20User%20Manual%20v1.pdf>

1.1.3 Obtaining authorisation signatures

Click on the 'Authorisation' tab on the NEAF application. Click 'Request' and then enter the email address of the person you want to sign the form and click 'Send request'. More than one electronic authorisation may be requested at the one time.

The recipient (collaborating researcher) will receive an automated email of an online forms electronic authorisation instructing them to log onto the Online Forms, open the 'Requests for authorisation' tab, click the 'Navigate' icon and click the 'Authorise Form' button.

For further information please see Section 'The Authorisation tab' in the User Manual:

<https://ethicsform.org/Au/Help/AU%20Online%20Forms%20for%20Research%20User%20Manual%20v1.pdf>

1.1.4 Transferring a NEAF to another user

To transfer the NEAF to a collaborating researcher click on 'My projects' 'Existing projects'. On the relevant application click on 'Manage', 'Transfer', and type in the person's email address and click 'Transfer to user'. **Do not create a submission code before sending it to a collaborating researcher.** In order to transfer the form to a recipient they must have an account on the Infonetica online form system.

For further information please see Section 'The transfer tab' in the User Manual:

<https://ethicsform.org/Au/Help/AU%20Online%20Forms%20for%20Research%20User%20Manual%20v1.pdf>

1.1.4.1 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 onto the Online Forms website to accept the application and access the form. When a person receives this notification from the originator of the NEAF they will be able to view and change the NEAF.

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 a submission code to be generated.
- Only the originator of a NEAF can create the NEAF submission code (however a collaborating researcher can create a SSA form submission code).

1.1.5 Retrieving a NEAF

For the originator of a NEAF to retrieve a NEAF that has been transferred, click on the 'Transfer' and then 'retrieve' button.

1.1.6 Transferring a NEAF permanently to another user

To permanently transfer the NEAF to a collaborating researcher, follow the steps outlined above. Once the collaborating researcher has accepted the form, the originator of the NEAF must return to the "Transfer Page" for the application and click on "Permanently Transfer This Form". A NEAF that has been permanently transferred cannot be retrieved.

1.1.7 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 Infonetica online NEAF portal) you will need to import this as an .xml file into the Infonetica NEAF portal in order to complete your application and access the SSA form. To do this you will need to save your NHMRC NEAF application as an xml file.

1.1.7.1 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 'My project' page on the Infonetica NEAF website and then click on 'Import xml (NEAF & other forms)' to import your NHMRC NEAF into the Infonetica NEAF portal. You can then complete your application as per usual.

For further information please see Section 'Importing the NEAF from www.neaf.gov.au' in the User Manual:

<https://ethicsform.org/Au/Help/AU%20Online%20Forms%20for%20Research%20User%20Manual%20v1.pdf>

1.1.8 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 'Manage categories' under 'Project categories'. Expand the category the project is stored in and tick the project you want to move and transfer it to the relevant category.

For further information please see Section 'Project categories' in the User Manual:

<https://ethicsform.org/Au/Help/AU%20Online%20Forms%20for%20Research%20User%20Manual%20v1.pdf>

1.2 Submitting an HREC Application to a reviewing HREC

Single Site Studies

Submit your application to the relevant HREC, after first determining the number of hard copies the HREC requires. Prior to submission of the application bundles, collate separate documents in order so that each bundle contains one copy of all required documentation.

On receipt of the collated hard copies of the application (with submission code), the HREC Administrator 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 may be sent from the HREC Administrator. The letter will include a **HREC Reference Number** and the meeting date at which the study 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 uploaded into the Australian Research Ethics Database (AU-RED).

For advice on where to submit the HREC application for ethical review refer to “*Where do I submit my protocol for ethical review*”: http://www.health.qld.gov.au/ohmr/html/regu/for_researcher.asp

Multi-centre Studies

Approximately five working days before the HREC application is ready to be submitted to a reviewing HREC, the CPI or delegated person should contact the Queensland Health Central Coordinating Service (CCS) line to request allocation of the application to a reviewing certified HREC on 07 3234 0654.

The Central Coordinating Service will require applicants to identify the HREC certification category that most closely applies to the project and the field of research from the lists on the REGU website: www.health.qld.gov.au/ohmr/html/regu/multicentre_research.asp.

When the CPI/delegated caller telephones the CCS to book an application for ethical review, the researcher will be asked a series of questions relating to the study. This is to ensure that the application is reviewed by an appropriately certified HREC. To facilitate the process, the CPI/delegated caller should have the NEAF in front of them. The call will take approximately fifteen minutes.

A standard email acknowledging receipt of a research application will be sent from the Central Coordinating Service. The email will include a **HREC Reference Number**, the HREC which has

been allocated the study for review (reviewing certified HREC), the HREC closing date for submissions and the HREC meeting date at which the study will be reviewed.

The Coordinating Principal Investigator will then need to submit all collated hard copies of the NEAF and supporting documentation as required by the reviewing certified HREC. The HREC Reference Number must be cited on all future correspondence with the HREC for ease of reference. All the information from the application will then be automatically uploaded into the Australian Research Ethics Database (AU-RED).

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

AU-RED is a secure web-based Research Ethics Database which links to the Infonetica NEAF form, allowing researchers to complete the NEAF and SSA application online. All details on your NEAF & SSA submission will be electronically uploaded 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).

1.4 HREC decisions

A final decision about the ethical acceptability of a research proposal should be made within 60 calendar days. The review '60 day' clock stops when information is requested back to the researcher by the HREC and re-starts when all the 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.

The progress of your application to an HREC may be monitored by logging in to your user account at www.ethicsform.org/au and clicking on the 'Project Progress' tab under the relevant application. This tab will only be visible if you have generated a submission code for your application, submitted the application to a reviewing HREC and the HREC administrator has logged the application onto AU RED.

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.

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 may be used to inform the decision of the Committee and the cost, if any, 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. At this time, the 60 day clock is stopped, and will not be restarted until the response from the applicant is received.

It is the applicant's responsibility to provide a prompt written response to the Committee's request. The investigator should not be asked to submit a revised NEAF but should be asked to provide a cover letter clearly addressing the questions asked by the HREC and must provide all the revised documentation in both 'track' changes and 'clean' forms.

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. In the latter case, the clock will again be stopped until such time as a response from the applicant is received.

The final decision of a HREC for a research proposal will be either “Approved” or “Not Approved”

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.

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).

A HREC “Approval” is not authorisation to commence research. Authorisation to commence the research is granted by the QH District CEO or delegate after the SSA has been reviewed by the Governance Office/r.

2. Research Governance Review

2.1 Site Specific Assessment Form (SSA Form)

A SSA form documents all aspects of research governance arrangements for a study at a particular Queensland Health site. The form can only be created out of the Infonetica NEAF. The NHMRC NEAF does not contain an SSA Form, so if used, it must be converted to the Infonetica NEAF. The site specific 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 study
- Compliance with relevant laws, policies and codes of conduct relating to matters such as privacy, confidentiality, consent, bio-safety, professional standards, and radiation safety

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 study 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 and services that will be required for the study, e.g. Heads of Departments or delegate/s and Director of Finance or delegate, as early as possible. Negotiations pertaining to the research governance processes should commence and run parallel to the HREC approval cycle. The final Declaration/s, however, may only be signed off once your HREC approval has been given.

2.1.1 To create a SSA Form

All studies

The SSA tab appears in the NEAF action tabs. Selecting this tab allows you to create a new Site Specific Assessment (SSA) for your project. On the SSA tab click 'Generate a new SSA'. Click on the relevant SSA Form, select 'Queensland' and 'SSA' and complete your form. The SSA Form is not available as a "stand alone" document – it can only be created out of the online form NEAF.

For further information please see Section 'The SSA tab' in the User Manual:

<https://ethicsform.org/Au/Help/AU%20Online%20Forms%20for%20Research%20User%20Manual%20v1.pdf>

The SSA form will be partially electronically populated 'on line' with information from your NEAF. However, you have a choice as to whether or not you accept the auto-populated data. To "de-select" the auto-populated data, simply click on the "Populate from NEAF" box. To edit the auto populated data, you must copy it, then de-select the auto populated data, and then paste and edit the text.

You will be required to complete those areas of the SSA that relate to your study 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 on the District budget, the District Finance Manager or delegate must sign off on the SSA.

Multi-centre studies

The Coordinating Principal Investigator (or this may be the Clinician Research Associate (CRA) for commercially sponsored clinical trials) should create a Site Specific Assessment Form for each site where the research will take place, by creating the required number of forms and transferring the form to the local Site Principal Investigator at each site to complete, create a submission code and submit to their local RGO.

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

2.1.2 Entering researchers onto the SSA Form

The easiest way is to go to "My Contacts" at the top of the page. Create a contact for each of the researchers associated with your study (include your own details). Then in the SSA Form, when details of researchers / contacts 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. Update details if appropriate. Then click on "Copy Contact 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.

2.1.3 Uploading Supporting documents

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

Click on 'My projects', 'Existing projects'. On the relevant SSA Form click on 'Manage', 'Documents' and then 'Upload' and then upload the relevant files from your computer. This ensures that the RGO receives all the supporting documentation. Note: Supporting documents can still be uploaded even after the SSA Form application has been submitted to the RGO

For further information please see Section 'The Documents tab' in the User Manual:

<https://ethicsform.org/Au/Help/AU%20Online%20Forms%20for%20Research%20User%20Manual%20v1.pdf>

2.1.4 Transferring a SSA form

To transfer a form to a collaborator, the collaborator must first register as a user of the Online Forms website. To register, go to: <https://ethicsform.org/Au/Users/CreateAccount.aspx>. You only need to register once.

Click on the relevant SSA 'Transfer' tab, type in the person's email address and click 'Transfer to user'. 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 create a submission code for 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.

2.1.5 Retrieving a SSA form

To retrieve a SSA Form that has been transferred; click on the 'Transfer' and then 'Retrieve' button.

2.1.6 Obtaining authorisation signatures

Click on the 'Authorisation' tab on the SSA Form application. Click 'Request' and then enter the person's email address who you want to sign the form and click 'Send request'. More than one electronic authorisation may be requested at the one time.

The recipient (collaborating researcher) will receive an automated email notification of an online forms electronic authorisation request, instructing them to log onto the Online Forms to open the 'Requests for authorisation' tab, click the 'Navigate' icon and click the 'Authorise Form' button.

For further information please see Section 'The Authorisation tab' in the User Manual:

<https://ethicsform.org/Au/Help/AU%20Online%20Forms%20for%20Research%20User%20Manual%20v1.pdf>

2.1.7 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, the recipient 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, create a submission code and print the SSA form and then submit the form to their local RGO.

2.2 What happens next with my SSA Application?

The completed SSA is submitted to the site Research Governance Office/r. Research Governance contact details are available on the REGU website

http://www.health.qld.gov.au/ohmr/html/regu/for_researcher.asp and are updated regularly.

2.3 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 study 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.

Final QH Institutional authorisation will be contingent on:

- HREC approval of protocol;
- Completed Site Specific Assessment (SSA) Form **and where required**
- Approval to access confidential health information for the purposes of research under the Public Health Act (Qld)
- Approval from QCAT for research involving adults with impaired capacity to consent
- Approval from the Clinical and State-wide Services (CaSS) to access tissue samples held by Queensland Health
- Approval from the Queensland Health Forensic and Scientific Services Human Ethics Committee, where studies involve material from coroners' autopsies

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

3. Access to Confidential Health Information for the Purposes of Research

If the research proposal involves access and use of identifiable or potentially re-identifiable data and confidential information, without consent, for the purposes of research, the provision of the Public Health Act 2005 (Qld), s282 must be considered. This includes, but is not limited to, health information held and owned by QH from the:

- Cancer Registry
- Perinatal Statistics Collection
- Pap Smear Register
- Register Screening Histories of Women
- Inpatient Data/records
- Pathology samples from QH Clinical and State-wide Services (CaSS)
- Any other Data base systems / hard copy charts held by QH.

Prior to commencing the research, the researcher must:

- Seek HREC approval for the protocol;
- Discuss data requirements with the data custodian;
- Complete a Public Health Act (PHA) application for release of data;
- Submit PHA application to the QH REGU
- Complete an SSA Form;
- Submit the PHA Approval letter with the SSA Form and all other required documentation to the site Research Governance Office/r.

Further information can be accessed at:

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

4. 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 Queensland Civil and Administration Tribunal (QCAT) is required. Where a person is over the legal age of consent but is unable to give consent, a written application to QCAT must be submitted after HREC approval is gained. QCAT can be contacted on:

Queensland Civil and Administrative Tribunal
Level 9
Bank of Queensland Centre
259 Queen Street
Brisbane, QLD 4000

GPO Box 1639
Brisbane 4001

T: 1300 753 228 (0830 hrs – 1700 hrs)

W: <http://www.qcat.qld.gov.au/index.htm>

Research Application Form:

http://www.qcat.qld.gov.au/Formsfinalcanbesaved/F16_Ap_con_c.rsrch.pdf

5. Research Involving Material from Coroners' Autopsies

Research involving access to coronial material must be referred to the Queensland Health Forensic and Scientific Services Human Ethics Committee (FSS-HEC) for ethical and legal approvals. This also applies to clinical research studies where there is a component involving coronial material. In this context, examples of coronial material include tissues from coronial autopsies, slides and blocks, blood samples, autopsy reports and other documents and data relating to coronial autopsies.

The use of material from coronial autopsies for research requires the approval of the State Coroner. If the research involves access to coronial documents approval as a 'genuine researcher' under s53 of the Coroners Act 2003 is also required. These approvals are subject to reviews by an ethics committee whose membership includes representatives of the State Coroner.

For further information please refer to the Forensic and Scientific Services Human Ethics Committee "Site requirements": Research Involving Material from Coroners' Autopsies: Advice to ethics committees and researchers:

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

6. Research Involving Pathology Samples

The Coordination Planning and Research Unit (CPRU) is responsible for managing Clinical and Statewide Services (CaSS) research activities. CaSS Authorisation to Proceed is required for any research project using information for which CaSS (including Pathology Queensland, Forensic and Scientific Services, Medication Services Queensland and other branches of CaSS) is the data custodian for any research project involving CaSS staff or resources.

New clinical trials or research projects must be approved by the Director of Pathology, local Laboratory Manager, relevant Supervising Scientist and Pathologist in charge of the departments involved (whichever is relevant).

For use of human tissue that is held by Queensland Health contact:

Clinical and Statewide Services: <http://www.health.qld.gov.au/qhcss/default.asp>

Clinical and Statewide Services: Coordination Planning and Research Unit:

<http://www.health.qld.gov.au/qhcss/research/info.asp>

Pathology Queensland: <http://www.health.qld.gov.au/qhcss/qhps/default.asp>

7. Low and Negligible Risk Research exempt from full ethical review

The National Health and Medical Research Council (NHMRC) "National Statement on Ethical Conduct in Human Research 2007" recognises that human research involves a wide range of activities that have variable risks and potential benefits. The "National Statement" establishes different levels of ethical review, based on the degree of risk involved. There are three levels of risk:

- Harm;
- Discomfort;
- Inconvenience

Researchers will need to check with the institution what processes are used for ethical review of low and negligible risk (LNR) research and are encouraged to contact the local HREC office / RGO to gain an independent assessment of whether the study satisfies the criteria for alternate review rather than that of a full HREC before proceeding with their application.

The National Statement Section 2.1.7 describes research as “negligible risk” where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience to the participants. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk. The National Statement describes inconvenience as the least form of harm that is possible for human participants in research. The most common examples of inconvenience in human research are filling in a form, participating in a de-identified survey or giving up time to participate in a research activity.

Institutions may choose to exempt from ethical review research that:

- is negligible risk research and
- involves the use of existing collections of data or records that contain only non-identifiable data about human beings.

The National Statement Section 2.1.6 describes research as “Low Risk” where the only foreseeable risk is one of discomfort. Discomforts may include minor side-effects of medication, discomforts related to measuring blood pressure or anxiety induced by an interview. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.

Single site studies

For all low and negligible risk research studies, the following must be completed and submitted to the institution’s low and negligible risk review panel:

- “Checklist for Research that is Exempt from full HREC review”
http://www.health.qld.gov.au/ohmr/documents/low_risk_app.doc and
- “Application for Ethical Review of Negligible or Low Risk Research”
http://www.health.qld.gov.au/ohmr/documents/low_risk_app.doc

If the decision of the reviewing panel is unanimous that the protocol qualifies for negligible or low risk review, the RGO or delegate will advise the investigator that approval has been granted. At this stage the research may commence.

If the reviewing panel considers that the protocol poses more than low risk (even if unlikely), the protocol will not receive negligible or low risk approval and will be reviewed at a full meeting of the HREC.

The SSA component of the LNR research application must be submitted to the RGO at the site.

Multi-centre studies

To ensure standardisation of review and monitoring procedures, if a coordinating investigator wishes to process a multi-centre negligible risk or low risk research study through the single ethical review process, for review and approval by a certified HREC, a LNR research application form must be completed and submitted as per normal procedure for multi-centre studies for single ethical review through the QH Central Coordinating Service.

The SSA component of the LNR research application must be submitted to the RGO at each site after HREC approval is granted.

8. Exceptional circumstances exempt from full ethical review

All studies

There may be wholly 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. Note that application for 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.

Single Site Studies

Applications submitted to the local HREC 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;
- Study protocol and supporting documentation;
- A request for exceptional circumstances review in writing and containing the reason for requesting review under exceptional circumstances and justification for the request.

If the application qualifies for exceptional circumstances review, the HREC Chair will advise Coordinating Principal Investigator and the District CEO or Delegate, through the local RGO, of the recommendation to conduct the research and monitoring responsibilities. In such circumstances, the local site Principal Investigator/s may be exempt from completing an SSA form, subject to local administrative research governance requirements.

Multi-centre Studies

Applications submitted for review under exceptional circumstances should be submitted to the local RGO as per the normal single ethical review process for multi-centre research and should include:

- Completed NEAF or original submission if not on NEAF and time factor does not allow time for NEAF to be completed;
- Evidence of a certified HREC approval;
- Study protocol and supporting documentation

The RGO will review the application and make a recommendation to the District CEO or Delegate. In such circumstances, the local site Principal Investigator/s may be exempt from completing an SSA form, subject to local administrative research governance requirements.

If the study has not been reviewed by a certified HREC, the study must be submitted for single ethical review through the QH Central Coordinating Service with a request for review under exceptional circumstances.

9. Quality Assurance Activities

Where an individual / group approaches a HREC Administrator for advice on whether a project falls within the definition of research, and therefore whether an application should be submitted to the HREC, the individual / group should provide a brief outline of the study in writing to the HREC Office. For Quality Assurance activities (including clinical audits and quality assurance) individuals should submit their application to a local QA Committee or the institutional body authorised to approve QA activities.

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.

10. Amendments to Research Post-Authorisation

Investigators are required to obtain ethical approval before implementing any amendment to a previously approved study. There are five types of amendments:

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

10.1 Amendments to the research study which may affect the ongoing ethical acceptability of the study

All studies

These are amendments that, as a condition of HREC approval, the local site investigator (or Coordinating Principal Investigator for multi-centre studies) is required to submit a request for approval of the proposed amendment to the approving 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 study are considered major (substantial) amendments and should be reflected in a cover letter from the Coordinating Principal Investigator (multi-centre studies) or local Site Principal Investigator (single site studies), stating the changes and reasons for the changes. The cover letter and all updated supporting documentation should be uploaded onto the online forms by the Coordinating Principal Investigator (multi-centre studies) or local Site Principal Investigator (single site studies). Two copies of the updated documents should be provided – one with ‘track changes’ and one ‘clean’ copy. *A revised NEAF should not be submitted.* Hard copies of the cover letter and all relevant updated documents (e.g. protocol, participant information sheets etc) should also be submitted to the HREC coordinator as required.

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 study must also be submitted by the site Principal Investigator to the relevant site RGO, for the Health Service District noting.

For multi-centre, commercially sponsored clinical trials, a CRA may be involved in distributing information between the CP.I. and P.I.'s.

10.2 Amendments to the Research study which may affect both the ethical acceptability and site acceptability of the study

All studies submission to HREC

Amendments which may affect both the ongoing ethical acceptability and site acceptability of a study are considered major (substantial) amendments.

Where a proposed amendment to the research study may affect both the ethical acceptability and site suitability of the study, the Coordinating Principal Investigator (multi-centre studies) or local Site Principal Investigator (single site studies) must firstly submit an amendment request to the approving HREC as per *'Amendments which may affect the ethical acceptability of the study'*. The HREC will review the amendment request according to standard procedures and will notify the CPI (multi-centre studies) or local Site PI (single site studies) in writing of its decision.

Details of the amendments should be reflected in a cover letter from the Coordinating Principal Investigator (multi-centre studies) or local Site Principal Investigator (single site studies), stating the changes and reasons for the changes. The cover letter and all updated supporting documentation should be uploaded onto the online form by the Coordinating Principal Investigator (multi-centre studies) or local Site Principal Investigator (single site studies). Two copies of the updated documents should be provided – one with 'track changes' and one 'clean' copy. *A revised NEAF should not be submitted.* Hard copies of the cover letter and all relevant updated documents (e.g. protocol, participant information sheets etc) should also be submitted to the HREC coordinator as required.

Single site studies submission to RGO

Once the HREC approval has been given for the amendments, the local Site Principal Investigator will submit a copy of the HREC approval letter, a cover letter stating the changes and reasons for the changes and all updated supporting documentation to their local RGO for authorisation to implement the amendment at the site. The updated documents should also be uploaded onto the online form by the local Site Principal Investigator. Updated documents should be uploaded in two forms - one with 'track changes' and one 'clean' copy. Hard copies of the cover letter and all relevant updated documents must be submitted to the RGO, as required as per normal authorising RGO procedure.

Upon receipt of the amendment request, the RGO will review the amendment and determine whether District CEO or Delegate authorisation is required to implement the amendment at the Health Service District site.

The RGO will notify the local Site Principal Investigator as to whether or not authorisation has been granted for the amendment to be implemented at that site. Authorisation to implement the amendment will only be granted when evidence has been provided of HREC approval.

The site Principal Investigator may not implement the amendment until the RGO has provided written notification that the amendment has been authorised at the Health Service District site.

Multi-centre studies submission to RGO

Once the HREC approval has been given for the amendments, the CPI will provide the local Site Principal Investigators with a copy of the HREC approval letter, a cover letter stating the changes and reasons for the changes and all updated supporting documentation for submission to each RGO for authorisation to implement the amendment at the site. Updated documents should be uploaded onto the online form by the local Site Principal Investigators. Updated documents should be uploaded in two forms - one with 'track changes' and one 'clean' copy. Hard copies of the cover letter and all relevant updated documents must be submitted to the RGO, as required as per normal authorising RGO procedure.

Upon receipt of the amendment request, the RGO will review the amendment and determine whether District CEO or Delegate authorisation is required to implement the amendment at the Health Service District site.

The RGO will notify the local Site Principal Investigators as to whether or not authorisation has been granted for the amendment to be implemented at that site. Authorisation to implement the amendment will only be granted when evidence has been provided of HREC approval.

The site Principal Investigator may not implement the amendment until the RGO has provided written notification that the amendment has been authorised at the Health Service District site.

The local Site Principal Investigators will then notify the CPI of the outcome at their site.

For commercially sponsored clinical trials, a CRA may be involved in distributing information between the CP.I. and local site P.I.'s

10.3 Amendments to the research study which only affect the ongoing site acceptability of the study

All studies

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 study may be submitted directly to the Research Governance Office/r (by-passing the HREC), by the local site investigator, only when the amendment requires:

- No change to the authorised protocol; **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 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 study should be reflected in a cover letter from the local Site Principal Investigator, stating the changes and reasons for changes, and accompanied by all relevant updated documents (which have been uploaded through the online form by the local Principal Investigator). Updated documents should be uploaded in two forms - one with 'track changes' and one 'clean' copy. Hard copies of the cover letter and all relevant updated documents must be submitted to the RGO, as required as per normal approving RGO procedure. *An updated NEAF should not be submitted.*

If an amendment requires any change to section/s of the SSA Form other than those listed above, then the amendment request must be submitted by the Principal Investigator (or Coordinating Principal Investigator for multi-centre studies) to the approving HREC in the first instance.

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.

For multi-centre, commercially sponsored clinical trials, a CRA may be involved in distributing information between the CP.I. and P.I.'s.

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

All studies

Amendments which do not affect either the ethical acceptability or site acceptability of the study (as per glossary minor amendments) should be uploaded through the online form and submitted in hard copy to the HREC coordinator. These should include a cover letter from the Principal Investigator (or Coordinating Principal Investigator for multi-centre studies), stating the changes and reasons for changes, and all relevant updated documents. Updated documents should be submitted to the HREC administrator in two forms - one with 'track changes' and one 'clean' copy. *An updated NEAF should not be submitted.*

If unsure of the applicability of the amendment, local site investigators (or Coordinating Principal Investigators for multi-centre studies), are encouraged to contact the approving HREC Administrator to discuss the amendment.

For all studies, the outcome of the HREC review and any revised documentation pertaining to the research study must also be submitted by the local site Principal Investigators to the relevant site RGO, for Health Service District noting.

For multi-centre, commercially sponsored clinical trials, a CRA may be involved in distributing information between the CP.I. and P.I.'s.

10.5 Amendments for Urgent Safety Measures

All studies

Where it is necessary to eliminate an immediate hazard to the research participants, amendments to the research study 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 RGO.

For multi-centre, commercially sponsored clinical trials, a CRA may be involved in distributing information between the CP.I. and P.I.'s.

11. Extension of a research study to an additional site

Single site studies

Where a single site study is to be extended to additional site/s, the local PI will take on the role of the CPI.

If the original approving HREC is not certified to approve multi-centre research in the study field, the CPI will be required to submit the study to a certified HREC for approval. The CPI will be required to contact the Central Coordinating Service at QH REGU to determine which HREC will review the application.

If the original approving HREC is certified to approve multi-centre research in the study field, and originally approved the study after 1 July 2010, the CPI will submit an amendment to the original approving HREC.

In all cases, for studies approved prior to 1 July 2010, the study will need to be submitted through the Central Coordinating Service for allocation to a suitable HREC (this is to ensure that the original reviewing HREC is certified in the study field to approve the research study)

The approving HREC will notify the CPI once HREC approval is granted.

The CPI will notify the local PI who will then apply to the local RGO for district authorisation.

The research will not be able to commence at each additional site until each respective district/ site has granted authorisation.

For those studies conducted under CTN/CTX conditions, the TGA must be notified of the new site/s by completion of the appropriate paperwork.

Multi-centre studies

If the original approving HREC is not certified to approve multi-centre research in the study field, the CPI will be required to submit the study to a certified HREC for approval. The CPI will be required to contact the Central Coordinating Service at QH REGU to determine which HREC will review the application.

Where a multi-centre study has been approved by a certified HREC in the study field and originally approved the study after 1 July 2010, and is to be extended to include additional site/s, the CPI will apply for approval from the approving HREC for the addition. This ensures that the approving HREC has the relevant information to correctly monitor the study.

For studies approved prior to 1 July 2010, the study will need to be submitted through the Central Coordinating Service for allocation to a suitable HREC (this is to ensure that the original reviewing HREC is certified in the study field to approve the research study)

The reviewing HREC will notify the CPI once HREC approval is granted.

The CPI will notify the local PI who will then apply to the local RGO for district authorisation.

The research will not be able to commence at each additional site until each respective district/ site has granted authorisation.

12. 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. 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. Fees may be levied by QH Forensic and Scientific Services to recover costs associated with ethical review and monitoring of research projects from applicants external to QH.

13. Clinical Trials

13.1 Clinical Trial Registry

In line with the National Statement on Ethical Conduct in Human Research 2007 Section 3.3.12 and the updated Declaration of Helsinki:

<http://www.wma.net/en/30publications/10policies/b3/index.html>, 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>

13.2 Clinical Trial Agreements

Queensland Health (QH) in collaboration with the Victorian Medical Insurance Authority (VMIA), interstate health departments, Medicines Australia (MA) and industry agencies have developed a set of uniformly accepted standard Clinical Trial Agreements (CTA's). These documents are available on the Medicines Australia website at:

<http://www.medicinesaustralia.com.au/pages/page39.asp>

The terms contained in the body of the standard CTA's must not be altered or amended in any way. Schedule 7 clauses are to be used for the inclusion of Sponsor unique operational requirements that must be accommodated to allow for the conduct of the trial. QH (in conjunction with VMIA and NSW Health) has pre-approved a number of Schedule 7 requests from individual pharmaceutical companies and clinical research organisations (CRO) for the commercially sponsored CTA. A commercially sponsored CTA with a pharmaceutical company must only contain the Schedule 7 Special Conditions that have been issued to that pharmaceutical company as approved by QH. If a site receives a contract containing non-approved Schedule 7 clauses, the contract must be submitted to QH REGU for legal review. A fee may be levied for this process.

Names of companies with QH approved Schedule 7 clauses can be accessed on the REGU website:

http://www.health.qld.gov.au/ohmr/documents/Schedule_7_Clauses.pdf

13.3 Parties to a Contract

The 'State of Queensland' is the contracting party for all QH agreements. The various state government departments (including QH) are not separate legal entities and cannot enter into contracts. Any wording which follows "The State of Queensland" is descriptive only and intended to assist the parties in identifying the relevant part/area/department within the State involved in the contract. QH should be described on all research contracts as: "The State of Queensland acting through Queensland Health (name of hospital/district) of (Address of Institution)".

13.4 Insurance

The Commercially Sponsored CTA and the CRO CTA both require the other party to have and maintain insurance with respect to its activities under the CTA's. The insurance requirements must be stated in Schedule 4.

The type and level of insurance required for each agreement will depend to some extent on the level and nature of the risks involved with the study. However, as a general guideline QH should include the following insurance requirements in Schedule 4:

The Sponsor/Local Sponsor must have and maintain for the term of this Agreement and for a period of 6 years thereafter the following insurances:

- (a) Clinical Trial/Product Liability insurance for an amount not less than \$10m per claim;*
- (b) Public liability insurance for an amount not less than \$10m per claim;*
- (c) Professional indemnity insurance for an amount not less than \$10m per claim;*
- (d) Workers compensation insurance in accordance with applicable legislation.*

It is recommended that you seek legal advice if you intend to include insurance requirements in Schedule 4 different from those specified above.

13.5 Clinical trials conducted under the CTN Scheme

All Studies

The order of signing should be:

- Local Site Principal Investigator;
- HREC Chair / delegate;
- Institutional Authority Approving The Conduct Of The Trial;
- Trial sponsor

For guidance on the roles and responsibilities of the 'Sponsor' see Page 2 of the *Notification of Intent to Supply Unapproved Therapeutic Goods under the Clinical Trial Notification (CTN) Scheme*: <http://www.tga.gov.au/docs/pdf/unapproved/ctnform.pdf>

Single site studies

The sponsor should complete Sections 1.1 – 1.5 and submit the CTN Form to the Local Site Principal Investigator who then signs the form and submits it to the reviewing HREC. After the study has received HREC approval the HREC Administrator should submit the CTN Form to the institutional authority for signing.

Once signed by the institutional authority, the CTN Form is submitted back to the Local Site Principal Investigator for submission to the sponsor.

A copy of the completed, signed CTN Form should be submitted to the RGO for filing.

Multi-centre studies

A separate CTN must be created for all the Australian trial sites. The process is:

- The sponsor completes Sections 1.1 – 1.5 of each of the CTN forms except for the signature page Section 1.6
- Sponsor submits the CTN forms to the Coordinating Principal Investigator (CPI)
- CPI forwards the CTN forms to each local site Principal Investigator for signing for their site
- Local Site Principal Investigators signs the CTN and returns signed CTN form to CPI
- CPI submits the CTN forms to the reviewing HREC
- After the study has received HREC approval, the HREC Chair / delegate signs the CTN forms and then submits the CTN forms back to the CPI
- CPI submits CTN forms to each local site Principal Investigator for local institutional authority signing.

- Local site Principal Investigators submit signed CTN form back to CPI
- CPI submits the completed CTN Forms to sponsor
- Sponsor signs completed CTN forms and submits CTN Forms to TGA.
- A copy of all the completed, signed CTN forms are submitted to the CPI
- CPI submits the copy of the completed, signed CTN form to the local site PIs
- A copy of the completed, signed CTN Form is submitted by the Principal Investigator to the RGO for filing.

14. 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 Australian Health Ethics Committee (AHEC) Position Statement: Monitoring and reporting of safety for clinical trials involving therapeutic products MAY 2009 for reporting requirements.

http://www.nhmrc.gov.au/files/nhmrc/file/health_ethics/hrecs/reference/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.

14.1 Progress reports

All studies

Institutions are responsible for the ongoing monitoring of the ethical conduct of research studies for which they have granted ethical approval (National Statement 5.5). As a minimum, the institution will require at regular periods, at least annually, progress reports from investigators on matters including:

- Progress reports to date or outcome in the case of completed research;
- Maintenance and security of records;
- Compliance with the approved protocol; and
- Compliance with any conditions of approval.

The approving HREC determines the frequency, type and format of reporting and monitoring which reflects the degree of risk of the research.

Progress reports should be uploaded onto the online forms by the researcher.

Single site studies

The site Principal Investigator will send a progress report to the HREC. If the HREC has concerns regarding the progress report they will then forward a copy of the progress report review outcomes to the RGO for review by the clinical governance committee.

In very specific cases of high risk research, the HREC may recommend in its letter of approval that the RGO coordinate on-site monitoring at recommended intervals or randomly throughout the research study. The RGO will provide such on-site monitoring reports to the HREC. If a district/site considers that it cannot comply with the monitoring recommendations made by the HREC, then it should not grant authorisation of the research at the site / district.

The coordination of on-site monitoring by the RGO involves making the necessary arrangements for appropriate personnel (internal and external to QH) to conduct the monitoring activity within the given timeframe.

On-site monitoring, coordinated by the RGO, may include attention to:

- o auditing / inspection of research conduct in compliance with the agreed protocol and conditions of approval, including consent documentation, current number of recruits, commencement / completion / withdrawal dates;
- o auditing / inspection of research conduct in accordance with ICH GCP;
- o auditing / inspection of data storage and security
- o interviews (or other forms of feedback) with research participants.

Multi-centre studies

The local site Principal Investigators will send a progress report to the Coordinating Principal Investigator and local RGO. The CPI will coordinate the reports and send them to the approving HREC. If the HREC has concerns regarding the progress report they will then forward a copy of the progress report review outcomes to the CPI, to be submitted to the applicable local PIs and local RGOs, for possible review by the local clinical governance committee.

In very specific cases of high risk research, the HREC may recommend in its letter of approval that the RGO coordinate on-site monitoring at recommended intervals or randomly throughout the research study. The RGO will provide such on-site monitoring reports to the HREC. If a district/site considers that it cannot comply with the monitoring recommendations made by the HREC, then it should not grant authorisation of the research at the site / district.

The coordination of on-site monitoring by the RGO involves making the necessary arrangements for appropriate personnel (internal and external to QH) to conduct the monitoring activity within the given timeframe.

On-site monitoring, coordinated by the RGO, may include attention to:

- o auditing / inspection of research conduct in compliance with the agreed protocol and conditions of approval, including consent documentation, current number of recruits, commencement / completion / withdrawal dates;
- o auditing / inspection of research conduct in accordance with ICH GCP;
- o auditing / inspection of data storage and security;
- o interviews (or other forms of feedback) with research participants.

14.2 Final Reports

A report to document the completion of the study. Final reports should include the final study report or any publications that have arisen from the research findings. The submission of final reports should follow the same process as submission of annual reports.

Final reports should be uploaded onto the online forms by the researcher.

14.3 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. DSMB reports provided to the CPI / PI should be uploaded onto the online forms by the researcher.

For studies where there is no independent DSMB, the HREC may report safety concerns to the Institutional Clinical Review committee (or other similar committee). In some instances, the HREC may request an independent DSMB be set up to regularly review the study. Details on how to set up a DSMB can be obtained by contacting REGU on REGU@health.qld.gov.au or 07 323 40034.

14.4 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.

All studies

Please refer to the table of requirements for adverse event reporting to HRECs by investigators from the *NHMRC Australian Health Ethics Committee (AHEC) Position Statement: Monitoring and reporting of safety for clinical trials involving therapeutic products (MAY 2009)*:

http://www.nhmrc.gov.au/files/nhmrc/file/health_ethics/hrecs/reference/090609_nhmrc_position_statement.pdf

All reports, including the cover letter / reporting template, should be uploaded onto the online forms by the researcher. Researchers should request sponsors submit the reports in an electronic version as well as hard copy version, if requested by the reviewing HREC, in order for the researcher to be able to upload the reports onto the online forms.

Single site studies

As a condition of ethical approval for research, the site Principal Investigator must immediately report to the HREC anything which might warrant review of the approval of the study, including serious and unexpected adverse events (SAE's, SUSARS, SUDR's). Such events must be reported to the HREC in the format specified by the HREC and review outcomes should be forwarded by the Site Principal Investigator to the RGO.

The local Principal Investigator/researcher must capture and report AEs in accordance with the protocol, and HREC and institutional requirements. SAEs which occur at their site must be reported to the sponsor within 24 hours of finding out about the SAE, in accordance with the study protocol and GCP guidelines as adopted by the TGA.

Multi-centre studies

For multi-centre studies, the local PIs will send all AE & SAE reports as per the *NHMRC Australian Health Ethics Committee (AHEC) Position Statement: Monitoring and reporting of safety for clinical trials involving therapeutic products (MAY 2009)* to the CPI who will collate and submit these to the approving HREC for review.

In the instance of commercially sponsored clinical trials, the CRA may be involved in this communication.

15. Suspension or Withdrawal of Authorisation for a research

15.1 Suspension or Withdrawal of HREC approval

A HREC may consider it appropriate that the adverse event/s (including SAE's, SUSAR's, SUADR's) and/or monitoring reports requires the immediate suspension or discontinuation of the ethical approval of the research study 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 study at the Health Service District 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.

Single site studies

Where the approving HREC considers it appropriate that the adverse event/s and/or progress reports requires the immediate suspension or discontinuation of the ethical approval of the research study, the HREC should immediately notify the Site Principal Investigator and RGO. This should be followed by a notice in writing, within 3 working days.

An investigator cannot continue with the research if ethical approval has been suspended or withdrawn and must comply with any special conditions imposed by the HREC.

Upon receipt of the HREC decision to suspend or withdraw ethics approval, the RGO must promptly advise the QH District CEO or Delegate to suspend or withdraw authorisation to conduct the research at the HSD site.

Multi-centre studies

Where the approving HREC considers it appropriate that the adverse event/s and/or progress reports requires the immediate suspension or discontinuation of the ethical approval of the research study, the HREC should immediately notify the CPI who will notify the local Site Principal Investigators, who will then notify the local RGO. This should be followed by a notice in writing, within 3 working days.

An investigator cannot continue with the research if ethical approval has been suspended or withdrawn and must comply with any special conditions imposed by the HREC.

Upon receipt of the HREC decision to suspend or withdraw ethics approval, the RGO must promptly advise the QH District CEO or Delegate to suspend or withdraw authorisation to conduct the research at the HSD site.

A CRA may be involved in this process if the study is a commercially sponsored clinical trial.

15.2 Suspension or withdrawal of authorisation by the site at which the research is being conducted

Where the QH District CEO or Delegate is satisfied that circumstances have arisen as such that is no longer appropriate to conduct a research study at the site/district, the HSD may suspend or withdraw its authorisation to conduct the research at that District/site.

In such circumstances, the RGO is required to immediately notify both the site Principal Investigator and HREC. The RGO must consult with the HREC first to ensure the safety and welfare of research participants is protected. This notification must be confirmed in writing within three working days.

For multi centred studies the local PI must notify the CPI of the date and reason for the suspension or withdrawal of authorisation by the site. The CPI must then notify the approving HREC.

An investigator cannot continue with the research if the District CEO or Delegate has suspended or withdrawn authorisation for the research to be conducted at that site.

A CRA may be involved in this process if the study is a commercially sponsored clinical trial.

16. Study Closure/Termination at a site

Single site studies

Where an authorised research study is to be closed at a site, the site Principal Investigator must notify the approving HREC in writing. The investigator will also be required to notify, in writing, the RGO.

Where a research study at a site is terminated or suspended by the site Principal Investigator prematurely, the HREC and RGO should be promptly informed and provided with a detailed written explanation of the circumstances.

AU -RED must be updated accordingly by both the HREC and RGO.

Multi-centre studies

Where an authorised research study is to be closed at a site, the Site Principal Investigator must notify the CPI who will notify the approving HREC in writing. The Site Principal Investigator will also be required to notify, in writing, the RGO.

Where a research study at a site is terminated or suspended by the site Principal Investigator prematurely, the Site Principal Investigator must notify the CPI who will notify the approving HREC in writing, providing a detailed written explanation of the circumstances.

The Site Principal Investigator will also be required to notify, in writing, the RGO.

AU -RED must be updated accordingly by both the HREC and RGO.

17. Complaints

17.1 Complaints concerning the conduct of a project

Any concern, allegations or complaints about the conduct of a project must be reported, in the first instance, to the approving HREC institution's Designated Person for handling research complaints, including research misconduct, through the secretariat of the approving HREC and to the local site RGO where the complaint applies.

17.2 Complaints concerning the HREC's review process including the HREC's rejection of an application

Any concern or complaint about the HREC's review process should be directed to the attention of the Chairperson of the HREC, detailing it in writing.

17.3 Complaints concerning the RGO review process, including the District CEO or Delegate rejection of an application

The Site Principal Investigator may appeal the decision of the site-specific assessment. Any concern or complaint about the RGO's review process should be directed to the attention of the RGO, detailing it in writing.

18. Frequently asked questions (FAQ)

- i. **Do I have to use the Infonetica online forms NEAF?** Yes. If you have created a NHMRC NEAF you will need to import this as an .xml file into the Infonetica NEAF portal in order to complete your application. Please see below: *'What to do with NEAF applications created on the NHMRC NEAF portal'* for guidance.
- ii. **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 of the QH Central Coordinating Service. Most HRECs will give you the HREC Ref number AFTER you have submitted your application. Therefore, this box will usually be blank when you submit the form.
- iii. **NEAF 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 study. 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 Contact 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.
- iv. **NEAF Section 2.1:** All studies MUST have a Chief Researcher (Coordinating Principal Researcher / Investigator) even if the study is a single site study. For single site studies the Chief Researcher (2.1) and Principal Researcher / Investigator (2.2) will be the same. For multi-centre studies the Chief Researcher (Coordinating Principal Researcher / Investigator) is the investigator nominated by the research team (in collaboration with the sponsor) to be responsible for the coordination of the research study in Australia.
- v. **NEAF Section 2.4:** The Contact Person is the person who will be the liaison person between the research team and the HREC / RGO. This is usually the clinical study coordinator.
- vi. **NEAF Section 4:** Ensure all sites in Australia are documented on the NEAF. Only include overseas sites if the study is being conducted as per the National Statement Chapter 4.8 (when a researcher from an Australian institution proposes to conduct research in another country).
- vii. **NEAF Section 5.1:** If any elements of the research study have a clinical component 'Clinical research' must be ticked.
- viii. **NEAF Section 5.6:** Ensure that there is a demonstrated understanding of and respect for the knowledge systems, cultural practices, heritage, beliefs, experiences and values of Aboriginal or Torres Strait Islander individuals and communities for all research sites.
- ix. **NEAF Section 6.1:** All boxes must be answered either a), b) or c).
- x. **NEAF 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.
- xi. **Do I have to upload all the supporting documents onto the online forms?** Yes. This ensures that all documentation is automatically uploaded into AU RED and enables the HREC to have an electronic copy of all the documentation. Supporting documents can still

be uploaded even after the NEAF application has been submitted to the HREC. Supporting documentation includes progress reports, annual reports, SAE reports, DSMB reports and study amendments.

- xii. **How do I know the Participant Information Sheets are at a Grade 8 level of reading?**
In a WORD document, on the Tools menu, click Options, and then click the Spelling & Grammar tab. Select the Check grammar with spelling check box. Select the Show readability statistics check box, and then click OK. On the Standard toolbar, click Spelling and Grammar .When Microsoft Word finishes checking spelling and grammar, it displays information about the reading level of the document.
- xiii. **Why can't the site details e.g investigators be populated from the NEAF into the SSA?** This is because the designated persons on the NEAF are not the same as the SSA. For example, a person identified as an Associate Investigator on the NEAF may actually be a Principal Investigator at a site and therefore identified as a Principal Investigator on the SSA form
- xiv. **It is not clear the timing of research governance application in relation to the ethics application.** Although the negotiations regarding the SSA application should be commenced early, the actual submitting of the research governance documentation, including the SSA Form to the RGO, should not occur until after HREC approval has been granted. As a result of the HREC review, the SSA Form and supporting documentation may require changes; therefore it is not appropriate to submit the SSA Form for Research Governance review until after HREC approval has been granted. However, consultation with the supporting departments should occur as early as possible and begin prior to HREC submission to ensure all relevant services and resources are available and accessible.
- xv. **Does the NEAF have to be completed and a submission code generated for the SSA to be populated?** No, as soon as a SSA is generated it will be auto populated in certain sections from the NEAF, even if the NEAF has not had a submission code generated.
- xvi. **Do you have to submit a NEAF and SSA Form?** Yes, the NEAF (and supporting documentation) are submitted to the reviewing HREC for ethical approval and the SSA Form (and supporting documentation) is submitted to the local RGO for research governance review and recommendation to the District CEO for study authorisation.

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