

Health Service and Clinical Innovation

Office of Health and Medical Research

Queensland Health Guidelines for the Management of Investigator-Initiated Multi-Centre Research conducted at Queensland Health sites.

A tool for Coordinating Principal Investigators
and their research team.

Research Ethics and Governance Unit
Office of Health and Medical Research

Queensland Health

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Abbreviations

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| Accepting PI | A Principal Investigator who is participating in the study but does not have the CPI responsibilities. |
| Accepting Site | A site that is participating in a multi-centre research project, but which has not taken on CPI responsibility. |
| CaSS | Clinical and Statewide Services – including Pathology Queensland and Medication Services Queensland. Go to http://www.health.qld.gov.au/qhcss/ |
| CCS | Queensland Health Central Coordinating Service for Multi Centre Research. Go to: http://www.health.qld.gov.au/ohmr/html/regu/cen_coord_serv.asp |
| CPI | Coordinating Principal Investigator. The CPI Team is responsible for coordinating all HREC processes throughout the study, on behalf of the Accepting PI's over which the CPI has CPI responsibilities. |
| CRC | Clinical Research Coordinator. May also be referred to as Study Coordinator, Clinical Trials Coordinator or Research Coordinator |
| CTA or CTRA | Clinical Trials Research Agreement. Go to: http://www.medicinesaustralia.com.au/pages/page39.asp or for device trials: http://www.mtaa.org.au/pages/page283.asp |
| CRA | The Clinical Research Associate (CRA) is a Sponsor or Clinical Research Organisation (CRO) representative employed to monitor clinical trials. The CRA ensures compliance with the clinical trial protocol, checks site activities, reviews case report forms (CRFs) and acts as a communication conduit between sites and the sponsor organisation. |
| CRO | Contract Research Organisation. A research organisation which is contracted by the Sponsor to undertake management and monitoring of a research project. |
| CTN | A form used for <i>notifying</i> the TGA of a clinical trial – The “Clinical Trial Notification Form” Click on “Clinical Trials Forms” at: http://www.tga.gov.au/ct/index.htm |
| CTX | Clinical Trial Exemption Scheme: A form used for notifying the TGA of a research project for which TGA approval is required. Go to: http://www.tga.gov.au/ct/ctglance.htm and click on “Clinical Trials at a Glance” |
| CV | Curriculum Vitae. For QH Guidance on CV's go to: http://www.health.qld.gov.au/ohmr/documents/regu/gcp_sop_v1.pdf . |
| DORA | The QH “ D atabase O f R esearch A ctivity”: A QH sponsored website listing all research projects being conducted within QH sites. Permission must be obtained from the Sponsor to publish details on the website. The consent form is part of the SSA Form. |
| HOD | Head of Department. In the NEAF, Section 10, this is the person who is supervising / responsible for the <i>researcher</i> i.e. the PIs Head of Department, either in the Institution or University etc. In the SSA Form, section 21B, HOD refers to the Department Head/s at the site where the actual research is taking place e.g. an antenatal clinic, cardiac catheter laboratory etc. SSA Section 21C refers to the Heads of <i>Supporting</i> Departments at the specific site where the research is being undertaken. These are the departments that are providing services for the research study e.g. Medical |

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| | Imaging, Pharmacy, Pathology. |
| HoMER | Harmonisation of Multicentre Ethical Review: The objective of the Harmonisation of Multi-centre Ethical Review (HoMER) initiative is to enable the recognition of a single ethical and scientific review of multi-centre health and medical research within and/or across Australian jurisdictions. Go to: http://www.nhmrc.gov.au/health_ethics/homer/index.htm#1 |
| HREC | Human Research Ethics Committee |
| LNR | Low and Negligible Risk Research. This application form will soon be accessible via the "Online Forms" site, but is currently available at: http://www.health.qld.gov.au/ohmr/documents/low_risk_app.doc |
| NEAF | National Ethics Application Form |
| NHMRC | National Health and Medical Research Council. Go to: http://www.nhmrc.gov.au/ |
| Online Forms | The website containing the QH preferred version of the NEAF. Go to: https://www.ethicsform.org/au/SignIn.aspx |
| PI | Principal Investigator |
| PHA | Public Health Act. For further information on the implications of the Public Health Act regarding Research, go to: http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp |
| PICF | Participant Information Sheet and Consent form. May also be referred to as the "ICF" ("Informed Consent Form"). |
| QCAT | Queensland Civil Administration Tribunal (previously the Guardianship and Administration Tribunal). Go to: http://www.qcat.qld.gov.au/ , and search on "Research" |
| QH | Queensland Health |
| REGU | Research Ethics and Governance Unit. For QH REGU, go to: http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp |
| Reviewing HREC | For multi-centre studies, the reviewing HREC is the NHMRC certified QH HREC which, under the single ethical review process, has reviewed and ethically approved the study and has assumed responsibility for monitoring the conduct of the research being conducted at QH sites. |
| RGO | Research Governance Office/r |
| SAE | Serious Adverse Event |
| SSA | Site Specific Assessment Form |
| SUSAR | Suspected, Unexpected, Serious Adverse Reaction |
| TGA | Therapeutic Goods Administration: The TGA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances. Go to: http://www.tga.gov.au/about/about.htm |

Purpose and scope

The purpose of this document is to provide guidance to Coordinating Principal Investigators (CPI) undertaking Investigator-initiated multi-centre research in Queensland Health research sites.

It is acknowledged that the CPI may delegate some duties to other research staff such as a Clinical Research Coordinator (CRC), Research Assistant or Project Officer and so this document also provides guidance to these research staff. Although the majority of the work managing the study may be delegated to another member of the research team - such as a CRC - the *responsibility* for the study ultimately rests with the CPI. For this reason all references in this document regarding workloads and allocations of duties are directed to the CPI.

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Introduction

This document is designed as a reference guide to assist a Coordinating Principal Investigator (CPI) or delegate, of an Investigator-initiated multi-centre research study, in developing a work plan to ensure the study is coordinated in an organised and informed manner from study start up to completion.

Using this guide, the workload placed on a CPI or delegate, when taking on the responsibilities of coordinating a multi centre research project should not be significantly greater than the workload experienced prior to the introduction of single ethical review of multi-centre studies.

In this guide:

- the Coordinating Principal Investigator (CPI) or delegate is denoted as “CPI”
- the Principal Investigators at other participating sites for which the CPI has responsibility will be denoted as Accepting PIs.

The document is divided into three sections:

- Section 1 contains dot point “quick reference” summaries
- Section 2 provides greater detail to guide the researcher through the processes required
- Section 3 contains the Appendices referenced throughout the document.

Section 1: Dot Point Summaries

1 The First Approach

- Consider the number of sites involved in the study.
- Have all the sites have been chosen and “signed up”?
- What contract or agreement is required?
- If there is a Commercial Sponsor involved, to what extent will they be involved?
- What equipment / resources will be required e.g. scanner, fax machine?
- Consider the level of experience of the CPI team members who will be undertaking the majority of the CPI tasks.

2 Setting Up

- To start your study Start Up preparation, you need:
 - Contact phone numbers and e-mail addresses of all Accepting Principal Investigators (PIs) and their nominated “Site Contact Person”
 - CPI Communications and Documents Folders (*see Appendix 4*)
 - Agreement of roles and responsibilities and level of support provided to CPI team members outlined in dot point below.
- Create an e-mail group for the study for communication with all sites
- Scan and e-mail all outgoing correspondence for ease of communication.
- Send out an “Introductory” e-mail to the group, as per *Appendix 1*.
- Start setting up reminders in your calendar for future study related events.

3 Preparing the HREC Application

- Ensure all supporting study documents for HREC review are electronically uploaded into the “Online Forms” site with the NEAF (or LNR Form, once this is available on line).
- E-mail all study documents to Accepting Sites, to enable the Accepting PIs to electronically attach all documents to the SSA once the SSAs have been created.
- Send the Participant Information sheet and Consent Form (PICF) to all Accepting Sites for review and amendment with site specific clauses.
- If amending the PICF, the new PICF should be uploaded into the NEAF. Include the new version details when electronically attaching the amended documents. Footer details for the PICF should be as follows:

Master Patient Information and Informed Consent Form, Version x, Dated DD/MMM/YYYY. Page 1 of X

- Ensure that any sub-studies or study addendums and their accompanying documentation are electronically attached to and included in the NEAF.
- CVs of PIs only should be uploaded into the “Online Forms” site with the NEAF, by the individual site contact persons, and the investigators name and site name inserted into the “Description” box.

- If hard copies of signatures are to be used, the CPI must wait until after all electronic signatures have been collected, obtain the submission code, then save the NEAF as a PDF document and email to Accepting PI's to enable them to sign a hard copy of the signature page that will have the submission code at the base of the page.
- Once signed, the Accepting PI should scan the signature page and upload it into the "Online Forms" site with the NEAF or post the signature page to the CPI for uploading electronically and insertion in the NEAF prior to photocopying.
- The Protocol Signature page (if required for HREC submission) should be e-mailed to all Accepting PIs for signing and either uploading with the NEAF or e-mailing back to the CPI to enable the CPI to upload it with the NEAF. The Protocol Signature page is really only required by the Sponsor.
- Do not make any changes to the NEAF after the electronic signatures have been obtained, or after the submission code has been generated, as any amendment to the NEAF will void the electronic signatures.
- Contact the Central Coordinating Service for allocation of the project to the first available appropriately certified Reviewing HREC.
- Contact the Reviewing HREC regarding their preferred templates for Annual Reports, SAE reports and any other site specific requirements.
- If applicable, CTN Forms for all participating sites are sent to the Reviewing HREC for signing before being signed by PI's at participating sites.
- Negotiations with the Sponsor regarding publication of study data on the QH Database of Research Activity (Q20 on the SSA Form) will be undertaken by the CPI and the outcome notified to Accepting Sites when the SSA Forms are created and sent out by the CPI.
- See *Appendix 13* for a summary of research project submission processes.

4 CaSS Applications, Guardianship Applications and PHA Applications within Queensland.

4.1 Clinical and Statewide Services (CaSS) Applications

- The CPI applies for CaSS Authorisation for participating QH sites only.
- Accepting QH sites still need to contact their local Pathology Queensland Laboratory manager to negotiate the conduct of the project at their site.
- The Authorisation to Proceed should be e-mailed to all participating QH sites as soon as it is received, to enable completion of the SSA at Accepting Sites.

4.2 Queensland Civil and Administration Tribunal (QCAT) Applications

- Each PI is responsible for making his/her own application to the Queensland Civil and Administration Tribunal for Guardianship approval of the study.
- QCAT applications are made after HREC approval has been received and before RGO Authorisation can be granted.
- Once received the QCAT Approval Letter should be processed at each site in the normal manner.

4.3 Queensland Public Health Act (PHA) Applications

- The PHA application submission occurs after HREC Approval has been received and before RGO Authorisation can be granted.
- One PHA Application will cover all participating QH sites.

- E-mail the scanned Approval Letter to all relevant sites.

5 Research Governance Review.

- The CPI creates the SSA forms for all the sites (including their own site) and permanently transfers the SSAs to the relevant Accepting PIs.
- If not previously emailed, the CPI should email all supporting study documentation to the PIs to enable them to electronically upload supporting documentation to the SSA Form.
- Inform the Accepting PI that the SSA should not be given a Submission Code until the Approval Letter from the Reviewing HREC has been issued as there may be changes to the Protocol, NEAF and PICF that will affect the SSA.
- Each site will “localise” the PICF by adding their site contact details, inserting site specific footer information. However, the PICF footer should still retain the reference to the Master Copy version details and date (see dot point below).
- The “site specific” PICF footer details should be as follows:
Master Patient Information and Informed Consent Form, Version x, Date DD/MMM/YYYY. Page 1 of X
(Site name) Patient Information and Informed Consent Form, Version x, Dated DD/MMM/YYYY
- It is each site’s responsibility to upload the localised PICF, Master PICF and all other study documentation including the HREC Approval Letter onto the “Online Forms” SSA for submission to the RGO.
- Ensure the Accepting PI’s (and Sponsor, if applicable) are aware of the DORA requirements (SSA Q20).
- The CPI will arrange for any legal review of the contracts through their site RGO, if non standard contracts are being used (QH sites only).
- The Medicines Australia “Forms of Indemnity” are required and should be sent directly to the sites by the CPI and returned directly to the CPI. If the CPI is a QH employee, and all Accepting PI’s are QH employees, a Form of Indemnity is not required.
- Study budgets are contained in the contract and are dealt with at a site level not by the CPI.
- Once the SSA and supporting documents have been reviewed and approved by the RGO, the site will return a copy of the authorisation letter, the original signed site CTN (if required), the original signed Contract and Indemnity Form (if required) to the CPI so the commencement of the study can proceed after these requirements have been fulfilled and completed.

6 Post Approval Amendments

- The CPI is to notify all sites of forthcoming amendments to the Protocol, PICFs or any other study documents.
- The CPI will modify the study documents as appropriate, electronically upload the documents into the “Online Forms” site, via the NEAF that was submitted for the study, and submit these to the Reviewing HREC for consideration and approval.
- Ensure document version details are updated and noted on all amended documents.
- Scan the Approval Letter once received, and e-mail to the Study Group along with the approved amended documents.
- Remind Accepting PI’s that changes to the Amended Master PICF must be made to the site specific PICF at a local level, and forwarded to the Site RGO, along with the HREC approval letter.

- For any new sites being added to a study, check the status of the HREC that originally approved the study to see if that HREC is approved to review and manage multi centre research projects.
- For studies changing from single site to multi centre research, a new HREC number may be issued when the protocol is re-allocated to the HREC through QH CCS.
- A new application may need to be made to a different Reviewing HREC if the original HREC is not approved to review and manage multi centre research projects.
- The addition of the new site may only need to be treated as an amendment to the study if the Reviewing HREC has approval to review and manage multi centre research.

7 HREC Reporting Post Approval

7.1 SAEs and SUSARs

- Participating sites must report all local SAEs / SUSARs to the CPI, Reviewing HREC, and local RGO within 24 hours of finding out about the SAE or SUSAR.
- The Reviewing HREC should correspond directly with the PI at whose site the SAE / SUSAR occurred, and the site should send copies of the HREC Acknowledgement letter to the CPI.
- If the Reviewing HREC sends the Acknowledgement Letter to the CPI, it is scanned and e-mailed to the appropriate site contact as per the usual process. Ensure the HREC Acknowledgement Letter indicates the sites at which the reported events occurred, or some other method of linking the Acknowledgement to the events.
- If the RGO at the site where the SAE / SUSAR occurred wishes to discuss the incident with the Reviewing HREC, they should contact the Reviewing HREC directly.
- It is the responsibility of the CPI to submit all other Safety Reports for HREC review.
- The Reviewing HREC may have preferred reporting templates and these should be used. Please refer to the requirements on the REGU website:
http://www.health.qld.gov.au/ohmr/html/regu/hrec_contacts.asp
- Record the SAEs and SUSARs from all sites in a spreadsheet that includes a record of when the events were notified to the Reviewing HREC. (See *Appendix 6*)

7.2 Other Safety Updates

- These are forwarded with a cover letter to the Reviewing HREC.
- On receipt of an Acknowledgement Letter from the Reviewing HREC, scan all documents and send to your e-mail group.
- File a copy of all correspondence in the CPI Correspondence File.

7.3 Annual Reports

- The annual report date is due on the anniversary of the date of the HREC Approval.
- Liaise with the Reviewing HREC, as to their preferred reporting format or refer to the requirements on the REGU website:
http://www.health.qld.gov.au/ohmr/html/regu/hrec_contacts.asp
- File a copy of all correspondence in the CPI Correspondence File. File a copy of the collated and individual (if you have them) Annual Reports in the CPI Documents File.

8 Study Termination

- The CPI will notify the HREC of the following:
 - Cessation of recruitment
 - Completion of the final patient
 - Formal closure of the study at all sites
 - Formal “End of Study” report.
- Accepting PIs are to contact their own participants and notify them of the termination or completion of the study and any follow-up that may be required.
- If there are changes to the role of CPI within the conduct of the study, Accepting Sites must be notified of the change by the original CPI.

Section 2: Step by Step Guidelines

1 The First Approach

To be a CPI, the whole research team should consider their current and foreseeable workload and objectively appraise the implications of taking on this additional role.

In making this decision, the following points need to be considered:

- The number of sites involved in the study
- Whether all the sites have been chosen and “signed up”
- Is a contract required? The pre approved “Medicines Australia” contracts are preferred, and if used unchanged, will not require legal review. However, if a non-standard contract is required, the services of the District Solicitor should be engaged.
- What equipment / resources will be required e.g. scanner, fax machine
- The level of experience of the member of the research team who will be undertaking the majority of the CPI tasks. (It is suggested that, for clinical trials, this person should have at least 18 months experience as a clinical research coordinator who has experience in HREC processes before being delegated CPI responsibilities, or should be mentored by such a person)

2 Setting Up

2.1 Develop a Communication Strategy

The CPI or delegate should compile a list containing the name, e-mail addresses and phone numbers of all site study contacts, the site Principal Investigators (PIs), and the study management team. This list is the **Master Contact List** for the study, and should be saved with all other study data – both on your computer and in hard copy.

Establish the manner in which you intend to communicate with the group. The easiest and most efficient way to communicate directly to all parties is to set up an e-mail group for the study. By using e-mail, you can attach copies of all communications to an e-mail and simply send it to the group. In this way, you are not spending a large amount of time attempting to fax documents and you are also able to communicate to a number of people in the one instance. This also allows communication to continue if the PIs nominated coordinator is away for any period of time. In addition, you have a record of what correspondence has been sent, and to whom.

You must have access to a scanner to use this method of communication.

Encourage Accepting Sites to set up a generic e-mail address, or alternate contact for their research site so that if the site contact person resigns from the site or takes leave, you can continue to communicate with the site without interruption. To create a generic e-mail address, follow these steps:

- Determine what you want the generic name to be (not too long though!).
- Search the “Groupwise” address book to see if the name is already in use.
- Your business manager or supervisor will need to send an e-mail supporting your request, and stating why a generic e-mail address is required. Include your proposed generic e-mail name in this e-mail.
- Send the e-mail to: infoservicecentre@health.qld.gov.au.

If you discover that a QH employee in your e-mail group has incorrect details in Groupwise, please e-mail them this link to enable them to update their details:

<http://connect.health.qld.gov.au/SSC/Authenticate.aspx?ReturnUrl=%2fssc%2fServiceCalls%2fUpdatePersonInfo.aspx>

2.2 Preparing your “Group” e-mail

To set up for e-mail communications, you will need to create a new address book for each study for which you have accepted the CPI role, which will allow you to keep your CPI e-mail groups separate from any other groups or address books you may have. Please see Appendices 5-7 for instructions on creating e-mail groups.

Within the “CPI” address book, you create your study specific ‘e-mail groups’ – which contain the e-mail addresses of all the parties you need to e-mail during each study. You should name the e-mail group according to either the protocol number or the study acronym. For example, you could call your Address Book “CPI Studies”, and create a group named for the protocol number: “CAT 1234”. The names included in this e-mail group would be the main contacts for each site participating in protocol CAT1234 (Principal Investigator and main CRC or site generic e-mail address for each site), and members of the study management team (if any).

You may like to create a sub group consisting only of the site contact persons at the Accepting Sites.

When you agree to become undertake CPI responsibilities for a second study, you would again set up an e-mail group for the other study (example) protocol “Galaxy 1” (using the study acronym) and this group would be saved in your “CPI” address book. Eventually your “CPI” address book will be a record of the different studies for which you have taken on the CPI responsibilities.

One word of warning – ensure you save or print all e-mail correspondence in your e-mail archive (or whatever other method you use to save communication) as, in QH, e-mails only remain in your in-box, sent-box and trash for 3 months. After this time, they are permanently deleted and cannot be retrieved. For guidance on saving e-mails, see *Appendix 8*.

2.3 Preparing the CPI Communications and Documents Folder

The best way to keep your documentation together is to obtain two folders. One Folder is for Communications and one folder is for Documents. These folders are separate from your own Investigator Site Binder. See *Appendix 4 for a suggested Index for these folders*.

In your CPI Document folder, there should be separate sections for all sites participating in the project – including your own site. Into each section, copies of participating site-specific documents should also be filed in chronological order. In the front of this folder file the CPI Agreement for easy reference.

In your CPI Communications folder, there should be separate sections for each Accepting site, and copies of any correspondence created or received as part of the CPI role should be filed in chronological order. It may also be helpful to create a spreadsheet to track correspondence created and received as part of the CPI role. See *Appendix 2 for an example*.

Do not mix these folders up with your Investigator Site Binders. You will still need to file your site specific documentation in your Investigator Site Binders as you would do normally.

2.4 First Communication

Consider sending out an “Introductory e-mail” to your newly established e-mail group. This will serve a number of purposes:

- enables you to introduce yourself as the CPI Team contact person for the study

- enables you to notify the sites of your full contact details (including fax and telephone numbers and postal address)
- enables you to inform the study centres of your role and responsibilities within the trial
- informs other study staff that they will need to be registered on the “Online Forms” web site in order to receive the NEAF (<https://www.ethicsform.org/au/SignIn.aspx>), and they must send you the email address that they have registered with, so that you can share documents with them
- allows you to alert study staff from other sites that you will soon be requesting Investigator CVs
- allows you to alert all the sites that access to the “Online Forms” NEAF is required by their sites’ PIs (if the PI is willing to sign the NEAF electronically) and the site CRC (for electronically uploading CVs etc)
- allows you to alert all the sites that access to the “Online Forms” is required by their sites’ Heads of Department (HOD) if the HOD is willing to sign the Site Specific Assessment Form (SSA) electronically
- it provides an opportunity to inform / remind other site study staff of their reporting responsibilities (see Section 6)
- allows you to notify the CRCs at the other Accepting QH sites that the CPI team will organise any legal review of the study contract if non standard contracts or Schedule 7 clauses are used
- it will test the efficacy of your e-mail group and the correctness of your e-mail addresses.

An example of this first communication letter can be found in *Appendix 1*. If you wish to use this letter, copy and paste it into a word document and attach it to an e-mail – it may lose some of its formatting if pasted directly into an e-mail.

2.5 Setting up your calendar for reminders

It is important that you have a system for reminding yourself of when required activities are due. You should set yourself a reminder 1 week prior to the action being required. For example:

- Set a reminder in your diary 1 week prior to the Annual Report e-mail notification being sent to Accepting Sites
- 4 weeks prior to its due date, e-mail the Accepting Sites a notification that their annual report is due, the date by which you want their completed report and attach the required Annual Report template that you will be using. Ensure that you stipulate the due date for the return of this document.
- It is important that you clarify whether the Annual Reports are to be returned to the CPI for collation prior to submission to the Reviewing HREC, or whether they are to be returned to the Reviewing HREC individually, with a copy to be sent to the CPI.
- 2 weeks prior to the due date, set a reminder in your diary to check which annual reports have been sent in by the Accepting Sites, and issue a reminder to those sites who have not responded.
- 1 week prior to the report being due, commence collating your Annual Report (if required) for final signing off by the CPI.

3 Preparing the HREC Application

3.1 The Protocol

The CPI is responsible for the development of the study protocol. For information regarding the content of a study protocol, please go the REGU website, to GCP SOPS no 4, *Appendix 1*.

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

It is not compulsory for the Protocol to contain a signature page, as by signing the NEAF the PI is attesting they are able to conduct the study according to the protocol and all required legislation.

3.2 NEAF Requirements

For submission to QH HRECs, the “Online Forms” version of NEAF is to be used to enable creation of the SSA Form (<https://www.ethicsform.org/Au/Forms/NeafFormList.aspx>). (Please note that for some research projects, the “Low and Negligible Risk” application form only, may be required. This form will soon be available from the “Online Forms” website, but currently is only available from the QH REGU website. Go to: http://www.health.qld.gov.au/ohmr/documents/low_risk_app.doc.)

- Complete all required sections of the NEAF, and include the Accepting PIs from all participating sites.
- Electronically upload all study documentation including Protocol, Investigator Brochure, Participant Information Sheets and Informed Consent Forms (PICFs), Investigator CVs (but not Associate Investigator CVs), questionnaires, participant diaries, advertisements etc. Ensure that you complete identifier details in the “Description” box to differentiate between documents of the same name (eg Investigator CVs, questionnaires)

If you create the NEAF on the NHMRC version of NEAF, documents cannot be uploaded and electronic signatures are not possible. However, it is a simple process to import the NHMRC NEAF into the “Online Forms” version. Please see the Researcher User Guide, Section 1.1.7.

(http://www.health.qld.gov.au/ohmr/documents/regu/resrch_user_guide_v1.pdf)

Do not open the file once you have saved it as an .xml file as this will corrupt the file and you will not be able to import it into the “Online Forms”.

For a summary of how and where to submit research applications, please see *Appendix 13*.

3.3 Answering NEAF Questions.

Under the single ethical review process, you may have some concerns regarding answering the NEAF questions. The following guidance is provided.

Q2.2: Principal Researchers. You are required to insert the contact details of ALL PIs participating in the study, not just the PIs at sites covered by your CPI responsibilities. (N.S 5.3.4)

Q2.3: Associate Researchers. At this stage, you only need to insert details for the Associate Investigators at the QH sites over which you have CPI responsibilities. With the introduction of the HoMER processes, this requirement will include all Associate Investigators from all Australian sites. (You do *not* need to obtain signatures on the NEAF from Associate Investigators at Accepting Sites – they will be collected on the SSA Form).

Q2.5: Other personnel relevant to the research project. You do not need to name individuals in this section. Please just insert the professional category to which these personnel belong e.g. Pharmacist, Neuropsychologist, Nuclear Medicine Radiographer.

Q2.6: Certification of Researchers / Investigators. The SSA Form, section 4.1 requires the Medical Officer Investigator to make a statement regarding their Queensland certification, so for this question in the NEAF, your response should outline any credentialing or certification requirements for the conduct of the study.

Q2.7: Training of Researchers. In this section, again, the response should be general, outlining any extra training required for the conduct of the study. A detailed response re training required at specific sites is covered in the SSA Form.

Q3.7: Does any member of the research team have a financial interest in the study? You must ascertain the response to this question from every researcher for whom you have CPI responsibilities.

The question has been inserted into the “First Communication between CPI and Participating Sites” letter (*Appendix 1*).

Q4.6: Reviewing HREC’s. In this question, you must insert all the Australian HRECs that are reviewing the study. However, at this time you will not know which QH HREC will be allocated to review the study. If you leave this question unanswered until after you have contacted QH CCS, and attempt to insert the allocated QH HREC, all the electronic signatures you have collected will be voided. If you do not obtain your submission code until AFTER you have been allocated the Reviewing HREC by QH CCS, you may not have enough time to collect all the required signatures. Therefore, it is suggested that you insert the QH HREC that you consider is *most likely* to be allocated the project, and comment on this in your HREC cover letter if the allocated QH Reviewing HREC is different from the one you nominated in the NEAF. If the allocated HREC is different from the one you have inserted into the NEAF, you should manually cross out the HREC on the NEAF and write in the correct one.

Q4.8: Have you previously submitted an application ...for ethical review of this research project to any other HRECs. This question does not ask if the research project has been submitted to other HRECs, it asks if YOU have submitted the research project to other HRECs for review. The answer to this question in most cases is “No”. Under single ethical review of multi centre research, as the CPI you should not have submitted this research proposal to any other HREC. The only exception to this is if this was previously a single site study and you are now adding additional sites and changing it to multi-centre research.

Q6.1: Participants. When answering this question, if you need assistance in answering later questions (Q 9.7) regarding Aboriginal and Torres Strait Islander peoples, please contact QH REGU to obtain contact details for the External Expert in this field.

Q6.7: Relationships between members of the research team and possible participants. For this question you should assume that all Accepting Sites will have similar categories of team members involved in the research project, so your answer should refer to a possible “clinician / patient” relationship.

Q6.13: Recruitment processes. In this section, write generally about the types of recruitment processes likely to be used. Site specific processes are addressed in the SSA Form.

Section 10: Signatures in the NEAF: There are three separate signature sections in the NEAF:

- 10a. Principal Investigators and Associate Investigators: The PIs signatures from all Accepting Sites are required. Associate Investigators are only required to sign the SSA Form, even though their name will appear in the NEAF Signature section.
- 10b. Student Supervisors: Signatures are required from student supervisors at all sites where a student is participating in the research.
- 10c. Head of Department: Only the signature from the Head of Department from the CPI site is required. Heads of Department from Accepting Sites will sign the SSA Form.

Please note: Where a researcher is also the Head of Department, the researcher cannot sign as the Head of Department. Their line manager must sign as the “Head of Department” in both the NEAF and the SSA Form.

3.4 Transferring the NEAF for Review by Principal Investigators at Accepting Sites

The completed NEAF should be sent for review by Principal Investigators at all Accepting Sites for which you have CPI responsibility. If you try to do this via the “Transfer” option in the “Online Forms” site, you can only send the NEAF to one PI at a time. This will create long delays if there are many participating sites (and therefore, PIs) for which you have CPI responsibility.

The most efficient way to send the NEAF out for review is to save it as a PDF document, and e-mail it out to all Accepting Sites, with a message giving them a specific time in which to review the document – include a statement that if they have not responded by (date), you will assume they have no amendments to the NEAF.

Instruct Accepting Sites that any changes to the NEAF should be saved in a “Word” document (since they will be unable to insert changes into the PDF document), and e-mailed to you but ensure that the Section and Page number of the change is included in the e-mail. This way if any PIs wish to amend the NEAF they can contact you directly. You can ascertain the importance of this proposed amendment, discuss it with the relevant PI and CPI and a decision can be made regarding implementing the change. This is also a good time to remind PIs to register on the “Online Forms” website to enable electronic authorisation of the NEAF, and to enable uploading of their Investigator CV’s.

Ensure you file a copy of this e-mail in the CPI Communications Binder.

If you do decide to send the NEAF for review via the “Online Forms –Transfer” option, the PIs must have registered on the “Online Forms” site in order to be able to receive the NEAF transfer. Do not obtain the Submission Code prior to sending the NEAF out for review - (wait until all changes are made and you are sending the NEAF out for electronic authorisation before requesting a Submission Code). Ensure you clearly state, in your NEAF Transfer Message Box, that you will be retrieving the NEAF on a certain date and that no other changes will be made to the NEAF after that time – including grammatical changes.

Once the documents have been sent back to you by the Local PIs, or after you have retrieved them, you can save them as a PDF File with the tracked changes. To do this, open the NEAF and click on “Print Draft”. Select “Download NEAF for Printing” and select the option of the “PDF with last 3 text changes”. Save the PDF to your desktop and review.

For further information, go to the “Online Forms’ User Guide, section 4.3, at <https://ethicsform.org/Au/Help/AU%20Online%20Forms%20for%20Research%20User%20Manual%20v1.pdf>.

For information to send to Accepting Sites on how to accept transferred forms, go to Appendix 11.

3.5 Legislative Requirements

For studies involving exposure of humans to ionizing radiation for Research researchers must obtain an independent assessment or verification by a Medical Physicist of the total effective dose and relevant organ doses for those radiological procedures that are performed specifically for the research protocol.

For studies involving access to identifiable or potentially re-identifiable confidential health information without consent a Public Health Act application will need to be submitted to the Research Ethics and Governance Unit post HREC approval.

Studies 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

For studies involving participants over the legal age of consent who are unable to give consent a written application to the Queensland Civil and Administrative Tribunal (QCAT) must be undertaken after HREC approval is given. At this time, each site must make their own application to QCAT.

For more information about Queensland State Legislative Requirements, go to: http://www.health.qld.gov.au/ohmr/html/regu/for_researcher.asp.

3.6 Sub-studies / Addendums

These applications are included in the NEAF with the original application. For all sub studies not contained in the NEAF a separate HREC application will need to be submitted and reviewed by an

HREC. The type of application form used will depend on the type of sub-study. There should be a separate PICF for all sub-studies.

3.7 Signatures and Electronic Authorisations

Do **not** obtain the submission code for the NEAF prior to sending it out to the PIs for their authorisation.

When the NEAF is sent out for *Review*, all parties are able to make changes to the NEAF. When the NEAF is sent out for *Authorisation*, it is automatically sent as a “read only” copy.

When sent for electronic authorisation, although the authorising PIs can type text into the NEAF, there is no “save” option, and any text inserted by someone who has received the NEAF for authorisation will not be saved. The only person who is able to make a change to the content of the NEAF after it has been sent for authorisation is the owner of the NEAF.

To obtain the signatures from PIs at other sites, there are two options:

- electronic authorisation of the NEAF or
- signed hard copy.

If PIs are registered on the “Online Forms” website, they will be able to sign the NEAF electronically. Please note that only the Principal Investigators and Chief Researcher can sign the NEAF electronically. If PIs are *not* registered on the “Online Forms” they will have to sign hard copies of the NEAF.

This is the process that you should follow when obtaining authorisations (consider sending a copy of *Appendix 12*):

- Once the NEAF is completed, send it for electronic authorisation first, and when all electronic signatures are in place, obtain the submission code.
- Save the NEAF as a PDF and email it to the remaining PIs who will be signing the paper copy. To create a PDF of the NEAF without the word “Draft” written on it, the NEAF must have a submission code. Then click on the “Submission” tab again and select the option to create a PDF of the NEAF. Select the option to generate a PDF “Without the last 3 text changes”, and follow the prompts.

In doing this, the electronic signatures will be included on the NEAF that has the submission code. Hard copy signatures will be collected later on the pages with the same submission code.

If you attempt to print the NEAF prior to obtaining the submission code, you can only print a draft version and the word “Draft” will appear across all pages. Draft “signature” pages will not be acceptable to a reviewing HREC.

Student Supervisors (where applicable) must sign hard copies of the NEAF signature page, scan the signature page and electronically attach it to the NEAF. Alternatively, they can post the hard copy to you for insertion into the NEAF prior to photocopying.

For instructions on how to obtain electronic authorisation of the NEAF, go to Section 4.4 of the “Online Forms” “User Manual:

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

Appendix 12 of this document may be copied and pasted into a “Word” document and emailed to PIs to assist them with the electronic authorisation process.

Remember:

- Multiple electronic signatures can be obtained simultaneously.

- The PIs will have to be registered on the “Online Forms” website in order to be able to electronically authorise the NEAF.
- The NEAF must be sent for Authorisation via the “Authorisation” option in the “Online Forms” site. If you send it via the “Transfer” option, the prompts for electronic authorisation of the NEAF do not appear. When the NEAF is sent out for Authorisation, the words “Read Only” appear in red font at the top of the document. Whilst it may appear that text can be edited in the NEAF, there is no “Save” option, so any changes attempted by PIs will not be saved.
- Ensure you give a time limit for the authorisations from the PIs and give yourself time to chase up those who have not responded..
- If hard copy signatures are required (i.e. if the PI is not registered on the “Online Forms” website), the submission code should be obtained, and the NEAF should be saved as a PDF, the signature page printed, signed, scanned and uploaded into the “Online Forms” site with the NEAF before sending it back to the CPI. In this way, the Submission Code will appear on the signature page. You will need to print this page for inclusion into your NEAF for submission. In your covering letter to the HREC it is advisable that you inform the HREC that this page has been uploaded and a printed copy is attached to the NEAF.

The most preferred option is that all signatures are obtained electronically through the “Online Forms” authorisation process rather than hard copy signatures.

The only person able to make changes to the NEAF after it has been sent for Authorisation is the owner of the NEAF. However, if any changes ARE made to the NEAF (by the owner) after it has been electronically authorised, all current electronic signatures are voided and will need to be sought again and a new submission code must be requested. All investigators must be notified of any amendments to the NEAF after they have reviewed it, and all signatures, both electronic and hard copy will need to be obtained again, on the correct version of the NEAF with the latest submission code.

Attaching documents to a NEAF with electronic authorisation does not void the signatures at any time.

3.8 Submission Codes

For information on obtaining a submission code, go to the “Online Forms” User Manual, section 4.5 <https://ethicsform.org/Au/Help/AU%20Online%20Forms%20for%20Research%20User%20Manual%20v1.pdf> or the “Online Forms” demonstration: <https://ethicsform.org/au/Help/Demo.aspx>.

If you need to make amendments to the form after the submission code has been obtained, amend the document, and obtain a new submission code. You do not need to duplicate the NEAF in order to make the changes. In your covering letter ensure you supply the correct submission code to the Reviewing HREC.

Documents may be electronically attached to a NEAF at any time - even after the submission code has been generated.

3.9 Investigator Curriculum Vitae’s

The CPI and all PIs (for whom you have CPI responsibility) named in the NEAF are required to submit their Curriculum Vitae (CV) for HREC review (unless they have already submitted their CVs to the Reviewing HREC within the last two years). The CVs should be electronically uploaded with the NEAF. When uploading the document, ensure that an entry is made in the “Description” box – so that the CV can be identified. The name of the PI and their site should be sufficient e.g.: “Dr Smith, Royal Queensland Hospital”. CVs should be no longer than 2 pages.

For guidance on the content of the CV, please see QH GCP SOP No 1 at this website: http://www.health.qld.gov.au/ohmr/documents/requ/gcp_sop_v1.pdf.

Uploading of the CVs should be performed by the Accepting site contact person when the NEAF is sent out for electronic authorisation from the PI. The CVs of Associate Investigators do not get uploaded to the NEAF. These CVs are attached to the SSA Form for submission to the site RGO.

3.10 Electronically Attaching Supporting Documentation to the NEAF

For information on electronically attaching documents to the NEAF, go to Section 4.2 of the “Online Forms” User Manual at Help section at:

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

At this time, documents electronically uploaded to the NEAF are NOT automatically transferred to the SSA Forms created. Therefore, you will need to ensure that you e-mail these documents to all Accepting Sites for which you have CPI responsibility, to enable them to upload the documents to their SSA Forms once they have been created.

If you decide to attach the documents to all the SSA Forms yourself, you will have to upload all documents to each SSA Form individually. You cannot do this as a single operation for multiple SSA forms.

3.11 Participant Information Sheets and Consent Forms

Some sites may have specific clauses to be inserted into the Participant Information Sheet and Consent form (PICF), such as clauses relating to contraception, particular cultural groups, or consent to contact external medical personnel. So as a priority, e-mail all sites as soon as possible and ask the sites to e-mail you any specific clause/s they want added. Inform the group that you will deal with the clinical wording of the document. Over time you can build a library of specific site clauses.

When you are inserting details into the Master PICF about the contacts for the study, the following responses or insertions are suggested:

- For queries regarding the research project, insert a comment to say that the names and contact details of the Local PIs will be inserted by Accepting Sites prior to submission to their site RGO.
- For queries about the approval process, or complaints about a researcher or the research project, contact the Reviewing HREC Administrator (insert a name and contact details).

Rather than leaving the response date from Accepting Sites as a vague future time, consider inserting a phrase that says:

“If you have not responded by (date: e.g. 1 week forward) I will assume that you have no site-specific clauses for inclusion in the PICF”.

The CPI will determine which additional clauses may be inserted into the PICF. Therefore, if you do receive any proposed clauses to the PICF, include these into your Master PICF. You may wish to annotate the clauses in such a way that it is clear they are specific to a particular site so that the CPI and Reviewing HREC can identify which site to discuss the clause with if there is a problem.

Ensure you have “tracked changes” and use the Comment icon to identify which site has requested which clause/s. Amend the clinical wording using the tracked changes tool. Try to have at least 2 weeks between your nominated cut off date for the return of site-specific clauses and the HREC submission date to enable the sponsor to review any changes to study documents.

When the PICF is ready for submission to the Reviewing HREC, save as a clean copy without tracking or annotation. Page 1 of the Master PICF and the section relating to site contacts in the body of the Master PICF should have areas left blank for insertion of investigator name/s, site contact details and complaint contact details, or contain a message indicating that these details will be completed by the sites for submission to their site Research Governance Officers (RGO’s).

The Master PICF footer should contain the following information:

Master Participant Information & Informed Consent Form, Version x, Dated DD/MMM/YYYY. Page 1 of X

The footer should contain the word “Master” for HREC submission (site specific version details will be added when submitting the approved Master version to the RGO at each site). When submitting for HREC review, ensure you submit the Study Master PICF – with correct version details and date.

If the Reviewing HREC requests changes to the Master PICF, the version details must be altered to reflect the new document, but always ensure the word “Master” remains in the footer. Once the amendments are completed, upload the PICF onto the NEAF in the usual manner. Re-submit to the HREC in the usual manner.

Attaching these documents will NOT impact on the submission code or negate the electronic signatures - provided that no changes are made to the actual NEAF content, no matter how minor those changes may seem.

3.12 Central Coordinating Service

For all multi-centre studies involving more than one QH site the study must be submitted through the QH Central Coordinating Service (CCS) for allocation to a certified Reviewing HREC. Do not ring the QH CCS until all signatures on the NEAF have been obtained, all paperwork is approved and in order, ready for submission, and that you have reviewed and decided on the “Research Category” accessed at: http://www.health.qld.gov.au/ohmr/documents/ccs_cats_v1.pdf and the ‘Field of Research’ accessed at: http://www.health.qld.gov.au/ohmr/documents/ccs_fields_v1.pdf.

It takes approximately 15-20 minutes to complete the questions for central allocation.

For more information on the QH Central Coordinating Service, go to:

http://www.health.qld.gov.au/ohmr/html/regu/cen_coord_serv.asp or call 1300 753 227 (1300 QLD CCS).

Once you have been allocated an HREC Reference Number by the CCS you should review the ‘Site requirements’ for the Reviewing HREC on the REGU website.

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

Contact the Reviewing HREC office to receive advice on submitting your application, such as the preferred method of submission and their preferred templates for Annual Reports and SAEs.

When the “Notification of Allocation” notice is e-mailed to you from the CCS, forward the e-mail to your Study e-mail group immediately, along with the Annual Report and SAE Reporting templates preferred by the Reviewing HREC. File the “Notification of Allocation” notice in your CPI Documents Folder.

3.13 CTN / CTX Forms

There is one CTN / CTX Form for every QH site participating in the research project. When these forms are required, the CPI team is responsible for creating one for each participating site, and for sending the completed forms to the TGA.

The “Sponsor” of clinical trials or research projects can either be individuals (eg medical practitioners), or bodies and organisations (eg hospital, area health service, non-government organisations) or companies (eg pharmaceutical companies). The sponsor carries the medico-legal responsibility for the study. If the CPI initiates and organises a trial or study, they may be defined as the Sponsor of the trial and will be responsible for the Sponsor’s functions. This includes where another party (usually a pharmaceutical company) used in the clinical trial, but has no other involvement in the conduct of the trial. Therefore, the CPI may sign the CTN / CTX Form as the Sponsor of the study, but will still need to sign the CTN / CTX as the PI for their own site.

Ideally, the order of signing will be:

- HREC Chair / delegate;
- Local Site Principal Investigator;
- Institutional Authority Approving The Conduct Of The Trial;
- Trial sponsor (must always sign last, as indicated on page 6 of the CTN / CTX (part 2) Form)

The Chairs of the QH certified HRECs have agreed to sign the CTN prior to the local PIs signing the document.

3.14 Forms of Indemnity

If the CPI and all Accepting PIs are QH employees, a Form of Indemnity is not required, as both the Sponsor (CPI or Queensland Health) and the PIs are all covered under QH indemnity.

If the CPI is a QH employee, and one or more PIs are NOT QH employees, the indemnification processes must be assessed on a case by case basis, under consultation from the District Health Solicitor.

3.15 The HREC Submission

Ensure that all study documentation has been received – either electronically or in hard copy. It is sensible to create a study spreadsheet, listing all the sites and all the study documentation sent or received. Keep this up to date and refer to it regularly. If there are some sites who have not returned all required paperwork in time for the HREC submission, those sites may be added in as an amendment to the study, at a later date.

If you receive an “Acknowledgement Letter” from the allocated HREC, scan it and e-mail it to the Study e-mail group. Place a copy in the CPI Correspondence and Documents File.

Scan and e-mail any correspondence from the HREC, including the requests for amendments to any study documentation. Ensure that any amended documents are sent electronically to your e-mail group, including the cover letters created by you, and that copies of all correspondence are filed in your CPI Correspondence Folder.

As soon as you receive the “Approval Letter” from the Reviewing HREC, scan it and e-mail it to the Study Group (and file in your CPI Documents Folder). This will enable them to finalise their Site Specific Applications. It is also prudent to update Accepting QH sites about the progress of any CaSS, PHA or QCAT applications. Remind all sites that their Annual HREC Reports are due in on the anniversary of the HREC approval date – NOT the date on which they receive site authorisation to conduct the research.

Please note that all QH HREC Approvals are for a maximum of three years. If an extension to the approval date is required, the CPI must write a cover letter from the CPI, explaining why the extension is required (eg low recruitment rates), and include an updated literature review, updated safety data for all clinical trials involving this investigational product and an assurance that there is adequate financial support, as per NEAF Q3.1-3.4.

3.16 QH Database of Research Activity (DORA)

Permission must be obtained regarding publication of study information on the DORA website. Although the questions relating to DORA are found on the SSA Form (Q20), the CPI should ensure all Accepting PIs are aware of the research data to be published, to enable them to answer the appropriate questions on the SSA Form..

4 CaSS Applications, Guardianship Applications and PHA Applications within Queensland.

4.1 Clinical and Statewide Services (CaSS) Applications

The CPI should take on responsibility for applying for CaSS Authorisation for participating QH sites only. Participating QH Sites will still need to contact their local Pathology Queensland Laboratory manager to negotiate the conduct of the project at their site. The Authorisation to Proceed should be e-mailed to all participating QH sites as soon as it is received, to enable the CRCs at those Accepting Sites to complete their site specific negotiations.

If a non QH Researcher is selected as the CPI, they will need to negotiate with a participating QH site to take on partial CPI Responsibilities. Negotiations should also include whether or not remuneration will be paid for this role.

4.2 Queensland Civil and Administration Tribunal (QCAT) Applications

Under current operating procedures at QCAT, each site must make their own application to the Queensland Civil and Administration Tribunal for guardianship approval of studies. The QCAT application requires a copy of the HREC Approval letter, so QCAT applications are made once HREC approval has been granted. Once received the QCAT Approval Letter should be processed at Accepting Sites in the normal manner.

4.3 Queensland Public Health Act (PHA) Applications

The PHA application submission occurs after HREC Approval has been granted. One PHA Application will cover all participating QH sites. E-mailing of the Approval Letter is as outlined above.

5 Research Governance Review.

5.1 The Site Specific Application

Negotiations pertaining to the research governance processes should commence and run parallel to the HREC approval cycle. Notify all Accepting Sites that you will be sending out their individual SSA Forms and give an expected date this will occur. In order to generate the SSA Forms from the NEAF you must have permanent ownership of the NEAF.

Local PIs should begin negotiations with relevant QH personnel responsible for resources that will be required for the study as early as possible e.g. Heads of Departments or delegate/s and Director of Finance or delegate.

The Reviewing HREC may request amendments to the Protocol or Master PICF may be altered before HREC approval is granted, and these amendments could result in changes to the study documentation which, in turn, may impact on the content of the SSA Form (e.g. study budget or resources required at the site). Advise all Accepting Sites not to generate a submission code for the final SSA until the Reviewing HREC has granted approval for the application. Do not forget to notify Accepting Sites of any amendments requested by the Reviewing HREC during the HREC review and approval process. Therefore, each PI should sign the final SSA Declaration/s and create a submission code for the SSA only after HREC approval has been given.

To create the SSA Forms, open the NEAF at the Index page, and click on the "SSAs" tab. Insert the number of SSAs you wish to create and click on "Create a new SSA Form". Don't forget to include your own SSA Form in the number of SSAs to be created.

Select an SSA Form and indicate in the location tab, which state the SSA will be submitted in and label the SSA with the relevant hospital name (e.g. Townsville Hospital, Gold Coast Hospital, etc). Once you have done this, the tab bar options increase.

Select "Transfer" and insert the e-mail address of site contact person that is specific to that particular SSA. Click on "transfer to user" and answer "yes" to the prompt. This action will *permanently* transfer the SSA to the nominated recipient. Once the recipient has accepted the SSA Form, the "owner" of the SSA form will alter from the person who created it, to the recipient. A copy of the NEAF will also be transferred with the SSA. Repeat this for all SSA Forms except your own. E-mail electronic copies of study documentation including the HREC Approval Letter to all Accepting Sites to enable them to electronically attach these documents to their SSA forms. Don't forget to inform the Accepting Sites that they can delete information relating to all researchers other than researchers from their own site.

Record on your communication planner / record that you have sent the SSA Form out to each of the Accepting Sites.

Please note that only people who have registered on the "Online Forms" site can accept and access the SSA Form.

If an extension to the ethical approval period has been granted, the CPI must send a copy of the HREC approval extension letter to PIs, who will forward this to their local site RGO, along with a updated study budget.

5.2 Participant Information Sheets and Consent Forms

Once the Reviewing HREC has approved the Master PICF the only changes Accepting Sites can make to the PICF are research governance changes – unless as otherwise indicated in the HREC Approval Letter.

This Site Specific Consent Document must contain:

- the name of the site from which recruitment is to occur (this may be on the relevant institutional letterhead);
- the relevant site specific contact details (such as the local principal investigator, who to contact if injury is sustained, the contact details of the person identified by the institution to receive complaints, etc.);
- the name and contact details of the Reviewing HREC
- the approved Master Consent Document version number & date and
- the Site Specific Consent Document version number & date.

You will also need to upload any documents that have been e-mailed to you from the HREC application – such as the Protocol, IB, HREC Approval letter. Master PICF(s), local site PICF(s) all study questionnaires, advertisements etc. Ensure you include, in the footer detail of the "local" PICF, the Master PICF version number and date as well as the site specific version number and dates, as per the Sponsor / CRO / HREC requirements. The Site PICF footer should contain the following details:

*Master Participant Information & Informed Consent Form, Version x, Dated DD/MMM/YYYY. Page 1 of X
(Site Name) Participant Information and Informed Consent Form, Version x, Dated DD/MMM/YYYY*

5.3 Contracts

The CPI is responsible for the preparation of contracts for Accepting Sites. Under the process of Single Ethical Review, there should only be one legal review of Research Contracts for each study. However, if standard contracts are used (as indicated on the Queensland Health REGU website: <http://www.medicinesaustralia.com.au/pages/page39.asp>) there should be no need for legal review.

If a non-standard contract is used, the CPI is to organise the legal review of the contract through their site RGO. Notify the other Accepting QH sites that you are organising the legal review of the non standard contract through your site RGO. Once the contract is approved by the QH District Solicitor, it will be sent back to the CPI for collection of signatures.

Each site requires a minimum of 3 original signed contracts. Original signatures are required on contracts. Each site will send 3 signed contracts (signed by the Sponsor (QH) and the PI) to their site RGO with the SSA. The site RGO will retain one contract and return two to the PI. The PI will keep one contract and return the remaining contract to the sponsor/CRO.

5.4 Indemnity Forms

The CPI will prepare Forms of Indemnity (if required), as outlined in Section 3.14.

5.5 Study Budgets

The CPI will determine the budget for each participating site, and email those details to each Accepting PI to enable them to complete their SSA forms.

5.6 RGO Authorisation

Once Authorisation has been received from the Site RGO, each site should ensure that the Authorisation Letter is mailed or scanned and e-mailed to the CPI. This letter will be filed in the "Documents" folder, under the specific site.

6 Post Approval Amendments

6.1 General Amendments

The CPI will notify all sites of any impending amendments to the Protocol, PICFs or any other study documents and will modify the study documents as appropriate, electronically upload the documents into the "Online Forms" site, via the NEAF that was submitted for the study, and submit these to the Reviewing HREC for consideration and approval. Version details should be modified and noted on all amended documents.

Once the Approval Letter is received back from the Reviewing HREC, it is scanned and e-mailed to the Study Group along with the amended documents.

Any changes to the Amended Master PICF will need to be made to the site specific PICF at a local level. All amended documents must be forwarded to the Site RGO, along with the HREC approval letter for those amendments. A copy of the RGO Approval Letter is forwarded to the CPI for filing in the "Documents" folder under the specific sites.

6.2 Adding a New Accepting Site

Scenario A: A study was approved prior to 01 July 2010 and now additional sites are to be added. The original reviewing HREC is now a certified HREC for multi centre research (MCR).

- If only one additional site is to be added, the new site will be treated as though it is a single site and will submit their own application to the original Reviewing QH HREC.
- If more than one extra site will be added (eg 2 new sites + original site), a new NEAF must be created and submitted via the QH CCS where a new HREC number will be allocated. Where possible, the original reviewing HREC will be used to review the study.

Scenario B: A single site study is being conducted at only one QH site, and the study was reviewed and approved by an HREC that is *not* certified to review and manage MCR. Extra sites are to be added

to the study. A new NEAF will need to be submitted via the QH CCS to an HREC that has been approved to review and manage MCR. A new HREC number will be generated for the study.

The original PI can continue to conduct the trial and will continue to report to their local HREC until such time as the study has been approved by the new HREC. The new PI cannot commence the study at their site until approval has been received from the new Reviewing HREC and they have received authorisation from their site RGO. The PIs may negotiate between themselves as to who will undertake CPI responsibilities.

Once the study has received approval from the Reviewing HREC as a multi centre study, the CPI must notify the original HREC that all HREC responsibilities for the study have now been transferred to the new Reviewing HREC. The PI from the original site should also notify their site RGO that there has been a change in the reviewing HREC.

Scenario C: As from 01 July 2010, if a new Accepting Site is added to a MCR study that is undergoing HREC review, or has received HREC approval by an HREC certified to review and manage multi centre research, the addition of a new site can be considered as an amendment to the study.

Scenario D: (Registry Studies) A Registry Study was approved prior to 01 July 2010. The original Reviewing HREC is now certified to review and manage MCR projects. Additional sites can be added as a protocol amendment.

Scenario E: (Registry Studies) A Registry Study was approved prior to 01 July 2010. The original Reviewing HREC is NOT certified to review and manage MCR but additional sites are to be added. A new NEAF is to be created and submitted to the CCS for allocation to an HREC that is certified to review and manage MCR.

Scenario F: (Research involving children) A new study is being conducted which will involve both children and adults. It will be an MCR study. If children are to be participants in an interventional study then the study will be allocated, via the QH CCS to The Royal Children's Hospital HREC – who will send the protocol to an external expert reviewer to review the study from the perspective of the adult participant. If the study does involve children but is non interventional, then the study will be allocated via the QH CCS, to the most appropriate certified HREC and the protocol will be sent to an external expert reviewer to examine the study from the paediatric perspective.

Scenario G: (Research involving children) If the study has been reviewed for adult participants only by an HREC certified for the review of MCR, and at a later stage the study is expanded to include paediatric participants, then two further options arise:

- The addition of the paediatric participants into an interventional study means that the study will have to be reviewed by The Royal Children's Hospital HREC. Whether the study is taken over by the children's HREC will need to be discussed between the original Reviewing HREC and the certified paediatric HREC
- If the addition of the paediatric participants is into a non-interventional study, then a notification is sent by the CPI to the Reviewing HREC to inform them of the new paediatric site. The protocol and paediatric PICF will be sent by the Reviewing HREC to the external expert reviewer. The Reviewing HREC will continue to oversee the study.

In those cases where a new site/s is added to a previously "single site" study, the PIs must determine between them as to who will take on the role of CPI.

In all cases where additional sites are added to an already established study, the following steps should be taken:

- The PIs should decide who will take on CPI responsibilities.
- The CPI must write a letter to the Reviewing HREC informing them of the inclusion of the new site/s.

- The cover letter should also include a comment that the addition of the new site/s may impact on the monitoring responsibilities of the Reviewing HREC.

Along with the cover letter from the CPI, the following documents must be submitted:

- CV of the new PI
- A letter from the new PI stating that they have read the protocol and can comply with the requirements for the conduct of the study at their site.

The CPI must also create an SSA and send it to the Accepting PI for completion and submission to their site RGO. All other procedures required for the RGO submission, as detailed in Section 5 above, should be followed.

7 HREC Reporting Post Approval

7.1 SAE and SUSARs

Each Accepting site has the responsibility for reporting, any Serious Adverse Events (SAEs) or Suspected Unexpected Serious Adverse Reactions (SUSARs) occurring at their sites, within 24 hours of finding out about it, to the following parties:

- the Reviewing QH HREC
- their Local RGO
- the CPI.

Please note: for local SAEs / SUSARs, the local PI is to submit *directly* to the QH Reviewing HREC and local RGO, with a copy of this correspondence to the CPI.

The Reviewing HREC should correspond directly with the PI at whose site the SAE / SUSAR occurred, and it is the responsibility of the site to send copies of the HREC correspondence to the CPI in the normal manner. If the Reviewing HREC sends the Acknowledgement Letter to the CPI rather than to the PI, the letter is scanned and e-mailed to the appropriate PI and the Acknowledgement Letter is filed in the CPI folder.

If the RGO from the site at which the SAE / SUSAR occurred wishes to discuss the SAE / SUSAR with the Reviewing HREC, they should contact the Reviewing HREC directly.

It is the responsibility of the CPI to ensure all other Safety Reports are submitted for HREC review. As per the May 2009 version of the NHMRC "Position Statement for Monitoring and Reporting of Safety for Clinical Trials involving Therapeutic Products", the Reviewing HREC must be notified "in a prompt manner" of "any material which impacts the continued ethical acceptability of a trial, or information that requires or indicates a need for a change to the trial protocol, including changed safety monitoring, in the view of the Investigator or Sponsor". For further information, please go to:

www.nhmrc.gov.au/health_ethics/hrecs/hrecalerts.htm

Once the HoMER process commences, there will be a standard reporting form for SAEs and SUSARs. Until this time, you may need to use the preferred reporting template for the Reviewing HREC. Ensure you obtain a copy of this template when you make your first contact with the Reviewing HREC, and send the template to all Accepting Sites. For information on the preferred SAE reporting format for all QH HRECs, go to the following website and look under "Site Reporting Requirements".

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

It would be good practice to record all site SAEs, SUSARs and any other safety reports received, on a spreadsheet, to enable you to keep track of all submitted safety information. See *Appendix 3* for an example of the CPI Record of Study SAEs and SUSARs

As soon as the SAE or SUSAR Acknowledgement is received, scan the Acknowledgement Letter and forward to the specific site/s (if not already sent to them), and file it in the CPI File. Ensure the HREC Acknowledgement Letter indicates at which sites the events occurred, or some other method of linking the Acknowledgement to the events.

If the Acknowledgement Letter relates to submission of 3-6 monthly line listings (if the research project involves a drug or device), scan the Acknowledgement Letter and e-mail a copy of the 3-6 monthly line listings and the Acknowledgement Letter to the E-mail Group. File the letter in the CPI file.

7.2 3- 6 Monthly Line Listings and other Safety Updates

On receipt of the 3-6 monthly line listings from the Sponsor forward these with a cover letter to the Reviewing HREC. On receipt of an Acknowledgement Letter from the Reviewing HREC, scan all documents and send to your e-mail group.

File a copy of all correspondence in the CPI Correspondence File.

7.3 Annual Reports

The annual report date is due on the anniversary of the date of the HREC Approval.

Determine, from the Reviewing HREC, the format in which they want the report submitted i.e. do they want all reports collated into one document or do they want each site's report individually (but submitted collectively)?

If the Reviewing HREC requests a collated report, send a reminder to all Accepting Sites 4 weeks prior to the due date of the report. Send additional reminders weekly to those sites who have not responded. File all annual reports as they are received. One week out, start collating the individual reports into the main report. File a copy of all correspondence in the CPI Correspondence File. File a copy of the collated and individual (if you have them) Annual Reports in the CPI Documents File.

8 Study Termination

At particular end points in the study, the CPI or delegate will notify the Reviewing HREC of the following:

- Cessation of recruitment
- Completion of the final participant
- Formal closure of the study at all sites
- Formal "End of Study" report issued by the CPI.

It is the responsibility of each site to contact their own participants and notify them of the termination.

Section 3: Appendices.

Appendix 1: First Communication between CPI and Accepting Sites

Caution: If you are copying and pasting this letter, paste it into a "Word" document and attach it to an e-mail. If you paste it directly into an e-mail, the formatting may be corrupted.

Salutation of choice

My name is (*insert name your name*), and I am your contact from the CPI site for the "*Study name*" study. The purpose of this e-mail is to outline some of the reporting procedures for this study, and proposed study timelines.

Study communications: I have set up an e-mail group listing the e-mail addressed of all the Principal Investigators and nominated Site Contact Persons for this study. I will be communicating with you by e-mail only, for this study. Please contact me by e-mail. In this way, we all have a copy of study communications.

THE HREC Application: The NEAF will be completed on the "Online Forms" version of NEAF. You will need to be registered on this site. If you are not registered, please go to the website and create your account: <https://www.ethicsform.org/au/SignIn.aspx>. Your PI and Heads of Departments will need to be registered on the site, too, to enable them to electronically sign the NEAF.

Please be aware that after registering on the "Online Forms" site, you must *activate* your account in order to be recognised as a user. *You must also send me the email address that you have used for registering on the "On Line Forms" site.* Once the Reviewing HREC has been allocated, I will contact them to find out their preferred templates for SAE / SUSAR reports and Annual reports and will send them to you.

All study documentation – including the HREC Approval Letter, will be uploaded into the "Online Forms" website, and linked to the NEAF.

Your response please: Please e-mail me, as soon as possible, your responses to the following three questions. Responses are required from every member of your research team:

1. "Does any member of your research team have a financial interest in the outcome of the research, or any affiliation with the providers of funding / support for the study"? (NEAF Q 3.7)
2. "Does any other individual or organisation have an interest in the outcome of this research?". (NEAF Q 3.8)
3. Does any member of the research team have any other general competing interests? (NEAF Q 2.2)

NEAF Signatures: Only the PI and Student Supervisors (if applicable) from your site will be required to sign the NEAF. The Head of Department signature (for the NEAF) is required from the CPI site only. Associate Investigators and Heads of Departments from your site will sign your SSA Form only.

If there are any students participating in this research project at your site, please inform them that their supervisors' signature will be required in the NEAF. This cannot be obtained electronically. The appropriate page must be printed out, signed and either scanned and uploaded with the NEAF or posted back to me for insertion into the NEAF prior to photocopying.

If the PI or Student Supervisor is likely to be absent when the NEAF signatures are required, please obtain a signed statement from them stating they are familiar with the protocol and are able to have the project undertaken at their site (or in the case of a student, they are able to provide suitable supervision). This letter should be signed, and either scanned and uploaded with the NEAF or posted to me for further processing.

Timeliness of Requested Responses: For each communication I send out to you, where a response is requested, I will nominate a “due by” date for your reply. If I have not received all requested information back from you, by the time the application is due to be submitted for HREC review, your site may be deleted from the application so as to prevent unnecessary delays in the HREC review process. Your site may be added to the study as a protocol amendment after the HREC review is completed, You may be responsible for any additional HREC Fees incurred as a result of this protocol amendment, as negotiated with the Sponsor.

Participant Information Sheets and Consent Forms (PICFs): I will e-mail you the Master PICF as soon as it is completed. In the meantime, if you have any clauses that you require to be inserted into the PICF please e-mail them to me. I will include them prior to sending you the PICF for review. You will have 5 days in which to review the PICF and insert any site specific clauses (if you did not e-mail them to me ahead of time). I will then liaise with the CPI to review the requested changes.

Study Contracts: As the CPI, our team will organise for the legal review of any non standard contracts or clauses.

CTN / CTX Forms: We will create the CTN Forms, organise for the HREC to sign them, and then send them to you for signing by thPI and the institution. Please ensure you return the CTN forms to me, so we can send them on to the TGA.

Site Contracts and Forms of Indemnity: Where appropriate, we will create the contracts and Forms of Indemnity and send them to you for signing. When completed, please return these to me.

The SSA Form: I will create your SSA Form and transfer it permanently to you to enable you to complete it and submit it to your site RGO. You cannot submit the SSA Form until the HREC Approval has been granted. I will also send you the appropriate responses to Q20 of the SSA Form.

Site Authorisation Letter: When you receive your Authorisation Letter from your site’s RGO, please send a copy to me.

SAEs / SUSARs occurring at your site: For any SAE or SUSAR occurring at your site, you must report it to the CPI, Reviewing HREC and site RGO within 24 hours of finding out about it. I will send you the reporting templates once the HREC process is completed. The Reviewing HREC will send the Acknowledgement Letter to you and you should send a copy to me. However, if the Acknowledgement Letter is sent to me instead, I will e-mail it back to you,. If your RGO wishes to discuss the SAE / SUSAR with the Reviewing HREC, they should contact the HREC directly.

Safety Updates and Line Listings: I will be responsible for processing these through the HREC and will e-mail correspondence to you.

Amendments: I will be responsible for processing study amendments. Copies of the amended documentation and all HREC correspondence will be e-mailed to you.

Annual Report: Please use the Preferred Template for the Reviewing HREC (I will send this to you). This report will be due on the anniversary of the HREC Approval. I will send you a reminder 4 weeks prior. Please check with your site RGO if they wish to receive a copy of your site specific Annual Report, as well as a copy of the Collated Report.

All correspondence from your site RGO: Please send a copy of all the correspondence to and from your site RGO to the CRA and to me, for recording and tracking purposes.

Please let me know if you are unsure of any study processes, or if you have any other queries.

Kind regards

Insert your name

Insert your position details

Appendix 2: Spreadsheet for Tracking CPI and Accepting Site Communications

| Microsoft Excel - Lead Site Communication Spreadsheet | | | | | | | |
|---|--|--|--------|--------|--------|--------|--------|
| File Edit View Insert Format Tools Data Window Help | | | | | | | |
| Calibri 11 B I U [Text Alignment] \$ % , +.00 +.0 [Number Format] | | | | | | | |
| C21 [Formula Bar] | | | | | | | |
| A | B | C | D | E | F | G | H |
| 1 | Study Name | | | | | | |
| 2 | Site 1 | Site 2 | Site 3 | Site 4 | Site 5 | Site 6 | Site 7 |
| 3 | Site numbers | 40003 | | | | | |
| 4 | Site Name | RBWH | | | | | |
| 5 | Site Contact Person | Jo Jackson | | | | | |
| 6 | Site Contact - Email | jo.jackson@health.qld.gov.au | | | | | |
| 7 | Site Contact - Phone | 3333 3333 | | | | | |
| 8 | Introduction Email sent (insert date under site numbers) | 24-Apr-10 | | | | | |
| 9 | Response received re Site specific clauses for inclusion in PICF? (insert date under site numbers) | 30-Apr-10 | | | | | |
| 10 | Protocol Signature page received (insert date under site numbers) | 30-Apr-10 | | | | | |
| 11 | NEAF Signed by P.I. (E=Electronic, H = Hardcopy) | E | | | | | |
| 12 | P.I. CV received (insert date under site numbers) | 30-Apr-10 | | | | | |
| 13 | Signed CTN Form received from Sites (insert date under site numbers) | 26-May-10 | | | | | |
| 14 | HREC Approval Letter emailed out (insert date under site numbers) | 30-May-10 | | | | | |
| 15 | Signed CTN Forms distributed. (insert date under site numbers) | 1-Jun-10 | | | | | |
| 16 | RGO Authorisation letter received from Sites (insert date under site numbers) | 24-Jun-10 | | | | | |
| 17 | RGO Authorisation letters emailed to Lead CRA (insert date under site numbers) | 30-Jun-10 | | | | | |
| 18 | | | | | | | |

Appendix 3: Spreadsheet for Tracking SAEs and SUSARs

Microsoft Excel - Lead Site Communication Spreadsheet

File Edit View Insert Format Tools Data Window Help

Calibri 11 B I U \$ % , +.00 +.00

H21

| | A | B | C | D | E | F | G | H | I | J |
|----|---|---------------|---------------|---------------------------------|---|---------------------------|---|-------------------|-------------------------------|---|
| 1 | Serious Adverse Event Record (Australian Master Copy) | | | | | | | | | |
| 2 | | Date of event | Name of Event | HREC meeting for Initial Report | Copy of HREC acknowledgement sent to Lead CRA | Follow up reports (dates) | Copy of HREC Acknowledgement sent to Lead CRA | Final Report date | HREC Meeting for Final Report | Copy of HREC Acknowledgement sent to Lead CRA |
| 3 | Site 1 | | | | | | | | | |
| 4 | example | 29-Jul-10 | Fractured Hip | Aug-10 | Aug-10 | Nil | | 31-Aug-10 | Sep-10 | 28-Sep-10 |
| 5 | Site 2 | | | | | | | | | |
| 6 | | | | | | | | | | |
| 7 | Site 3 | | | | | | | | | |
| 8 | | | | | | | | | | |
| 9 | Site 4 | | | | | | | | | |
| 10 | | | | | | | | | | |
| 11 | Site 5 | | | | | | | | | |
| 12 | | | | | | | | | | |
| 13 | Site 6 | | | | | | | | | |
| 14 | | | | | | | | | | |
| 15 | Site 7 | | | | | | | | | |
| 16 | | | | | | | | | | |

Appendix 4: CPI File Index (example)

CPI File Index

Correspondence Folder

1. Correspondence - General
2. Correspondence - HREC

Documents Folder

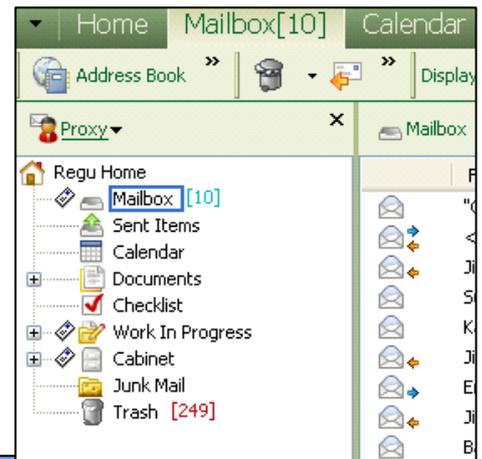
1. HREC Application documents including
 - Copy of HREC submission and NEAF
 - HREC Approval Letter / Notification of Commencement of Study
2. Essential Documents:
 - CTN / Indemnity-HREC only
 - Protocol and Protocol Amendments
 - Master ICFs and ICF Amendments
 - Investigator Brochure
3. State Specific Approvals (classified by State) eg:
 - QCAT Application / Approval (if required)
 - Pathology Queensland Application / Approval (if required)
 - PHA Approval (if required)
10. SAEs / SUSARs and Safety Reports
11. Annual Reports

You may also find it helpful to have separate sections for each participating site in which to file separate site specific communications.

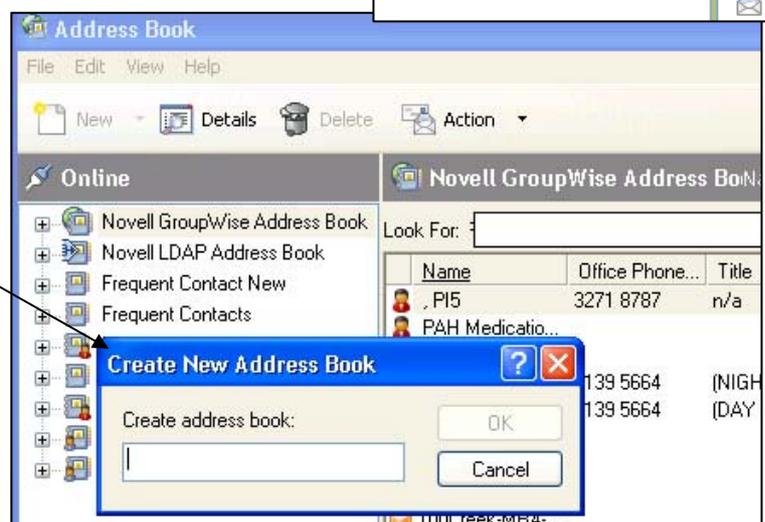
Appendix 5: Creating a New Address Book in Groupwise

To set up a new Address Book (you should only need to do this once):

- Click on the “Address book” icon in Groupwise (upper left side of the toolbar)

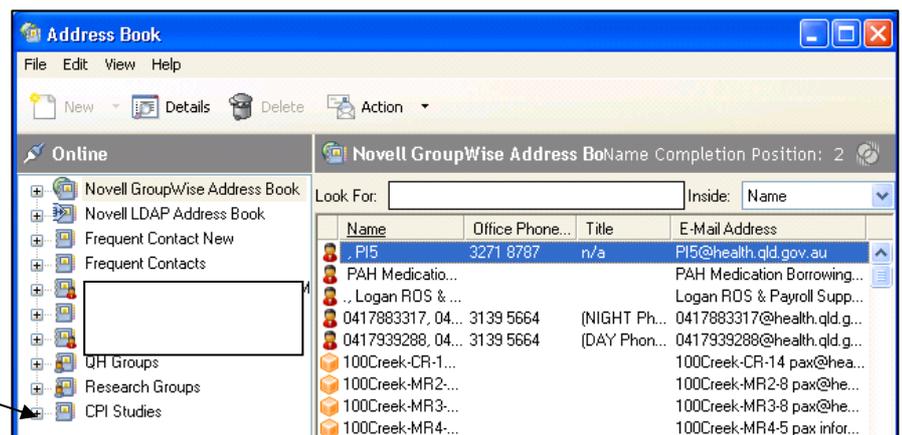


- Click on “file” and select “New book”. A new window will appear, called “Create New Address Book”



- Type in the name of your new address book (we suggest something like “CPI Studies”)
- Click “OK”.

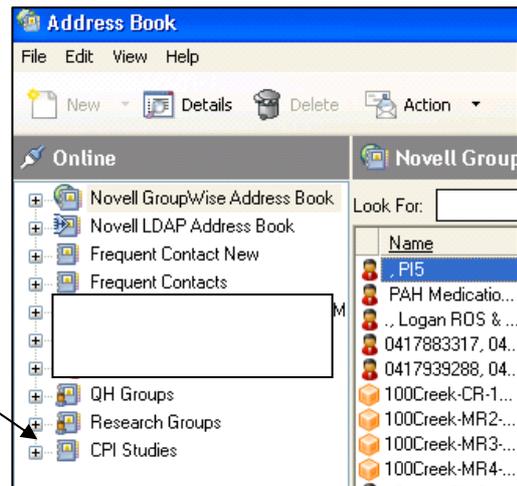
The new address book should now appear on the left hand side of your Groupwise screen. In this address book you will set up all your “groups” relating to the studies for which you are the CPI.



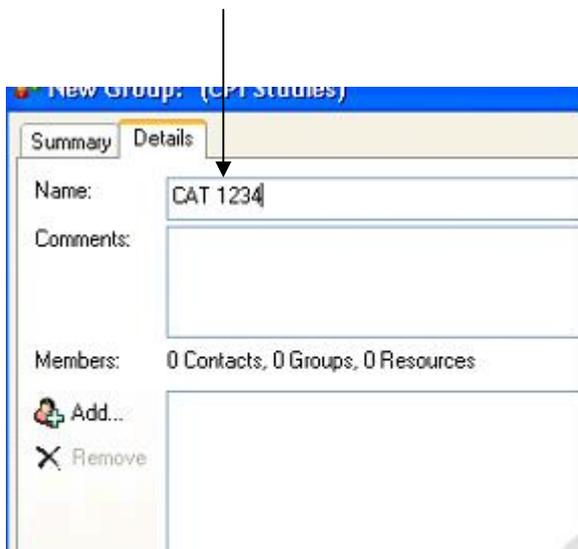
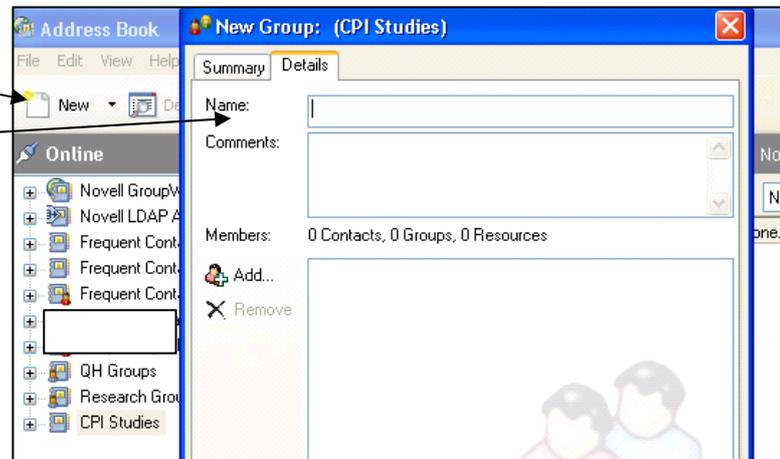
Appendix 6: Creating a New E-mail Group in Groupwise

To set up a new E-mail Group, do the following:

- Click on the “Address book” icon in Groupwise (upper left side of the toolbar)
- Select the Address Book in which you want the group to appear e.g. CPI Studies.



- Click on “New” (upper left) and select “Group” from the pop-up window.
- Click “OK”.
- A new window will appear, prompting you to name the new group.
- For simplicity, use either the Protocol Number (e.g. CAT 1234) of Study Acronym as the group name.



- Click “OK”.

- The Group should appear under the heading of “CPI Studies”.

The screenshot shows three overlapping windows. On the left is the 'Select Group Members' window with a list of contacts. In the middle is the 'Address Book' window showing a tree view with 'CPI Studies' expanded. On the right is a 'CAT 1234 (CPI Studies)' details window showing the contact's name and comments.

- Double click on the new group, or “right click” and select “details”.
- Select “Add”.
- A new window will appear (called “Select Group Members”).

- Click on the *QH employees* (one at a time) from the Groupwise address book. Ensure they appear in the right hand pane of the “Select Group Members” window, then click “OK” in the same window. The person’s name should then appear in the “New Group” window on the right.

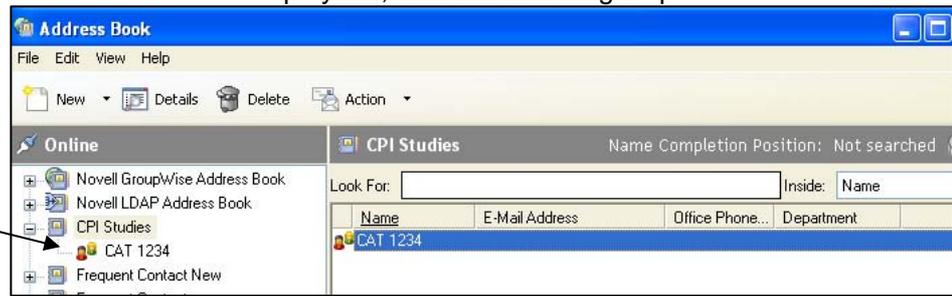
The screenshot shows the 'Select Group Members' window with three contacts selected in the 'Selected:' pane. The 'CAT 1234 (CPI Studies)' window now shows 'Members: 0 Contacts, 0 Groups, 2 Resources' and lists the two newly added contacts: 'To: QHB 17-CR' and 'To: QHB 13-CR'.

- Repeat this process for all QH personnel participating in the project.
- If an entry to the group is made in error, simply click on the incorrect entry to highlight it.
- The word “Remove” will appear in the left hand pane. Click on “Remove” to delete the incorrect entry.

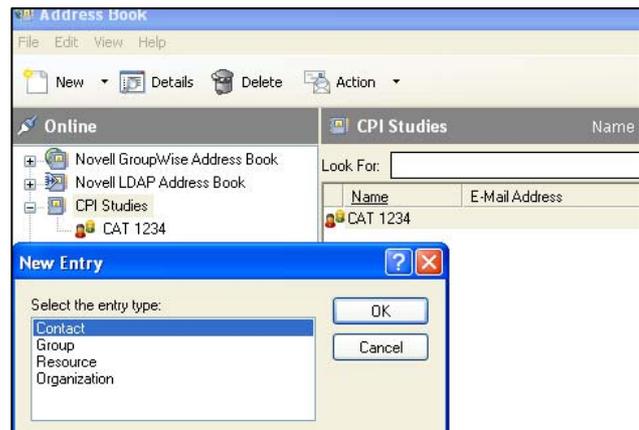
Appendix 7: Adding Non QH Contacts into Groupwise

To add in names of people who are not QH employees, take the following steps:

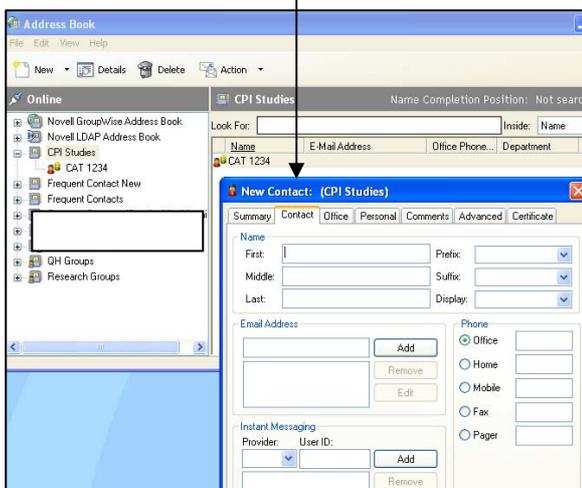
- Select the correct “Group” from your “CPI Studies” address book.



- Go to the upper left side of the tool bar and click on “New”, then select “Contact”.
- Click “OK”

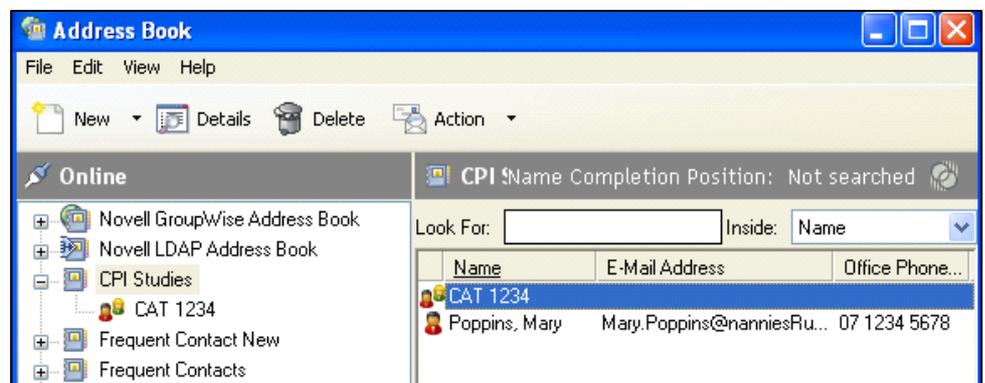


- A new window will appear with prompts to insert details for the Non QH Contact person.



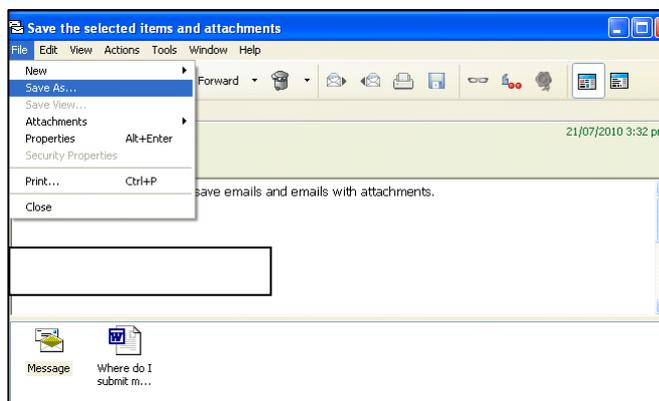
- Insert the contact details for each non QH study contact, one at a time, following the prompts.
- The contact will be stored in the “CPI Studies ” address book.
- When you click on “Add”, and the Address Book window appears on the left, go to the “Look In” tab, and select the “CPI” address book. All the non QH e-mail addresses that you have just entered will appear.

- Import the contact details into the “E-mail Group” for the correct study as per the instructions above.

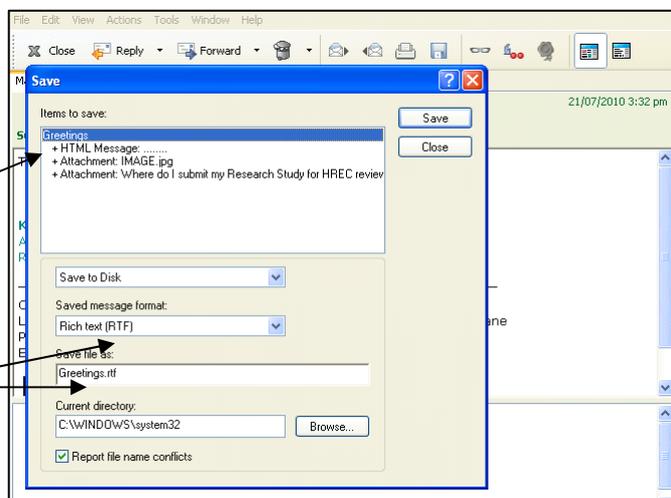


Appendix 8: Saving an E-mail Text as a “Word” document

Open the e-mail you wish to save and click on “File”



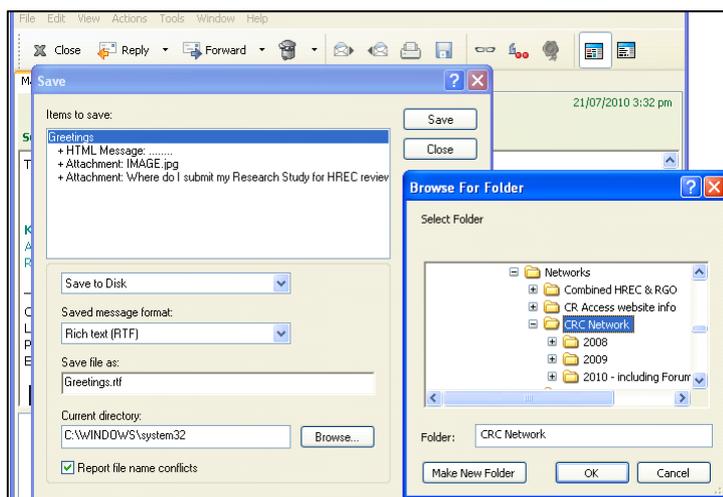
Click on “Save As” and you should see the following screen



Select the part of the e-mail you wish to save and click “Save”.

Ensure that the suffix of the document contains the descriptor “rtf”. If you do not include this, you will not be able to open the document when you have saved it.

Select the folder you wish to save it in by clicking “Browse”, find the folder in the list and click “OK”



Repeat this for all the components of the e-mail you wish to save

Appendix 9: Setting up a document to “Track Changes”

This tool is only available in “Word” documents.

Open the document in “Word”.

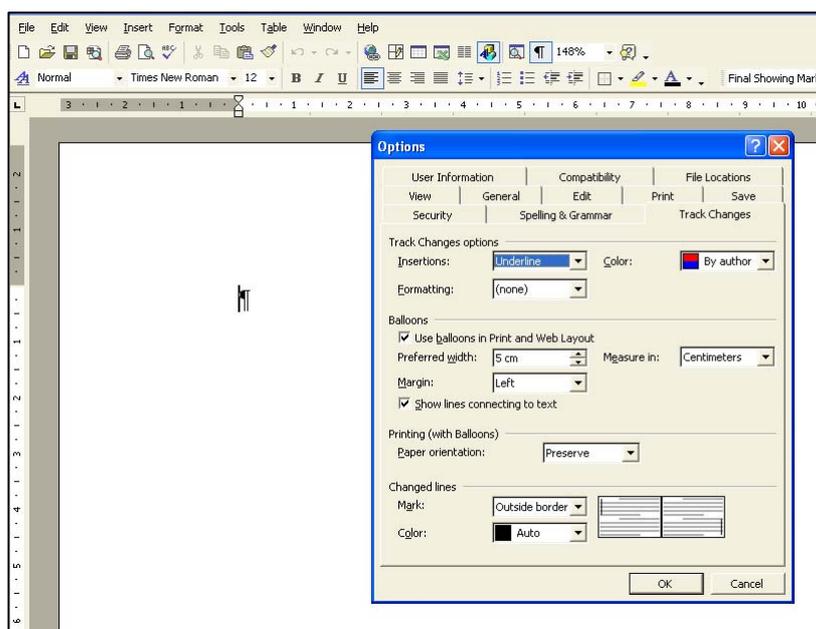
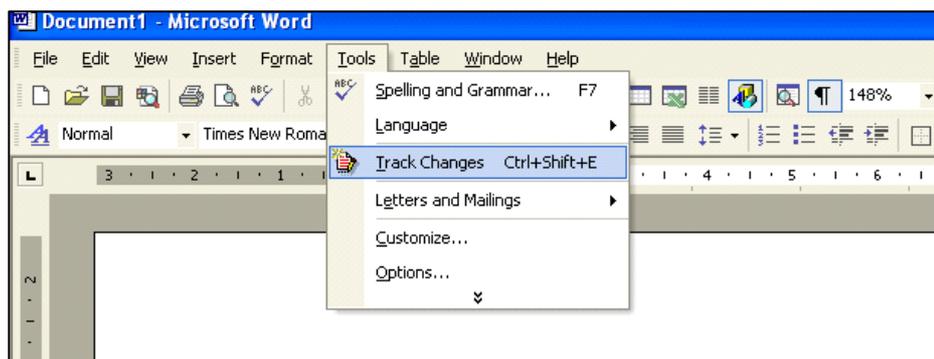
Simultaneously press on “Control, Shift, E”.

OR

Click on “Tools”

Select “Track Changes” and then click “OK”.

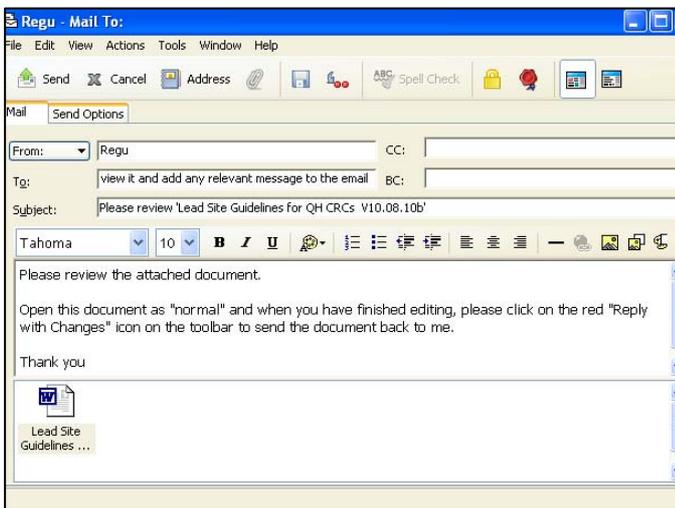
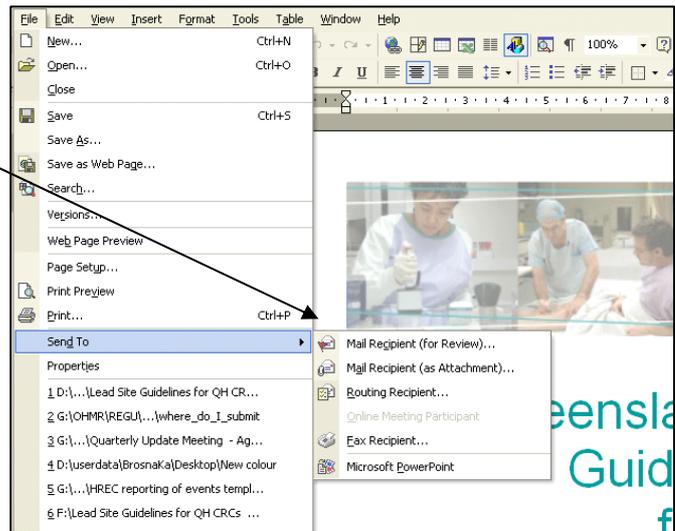
When you make any changes to the document, they should appear in a different coloured font, and an explanation of the change should appear in the side margins of the document. If you want to alter the options in “track changes”, click on “Tools”, and select “Options”



Appendix 10: E-mailing a Document for Review

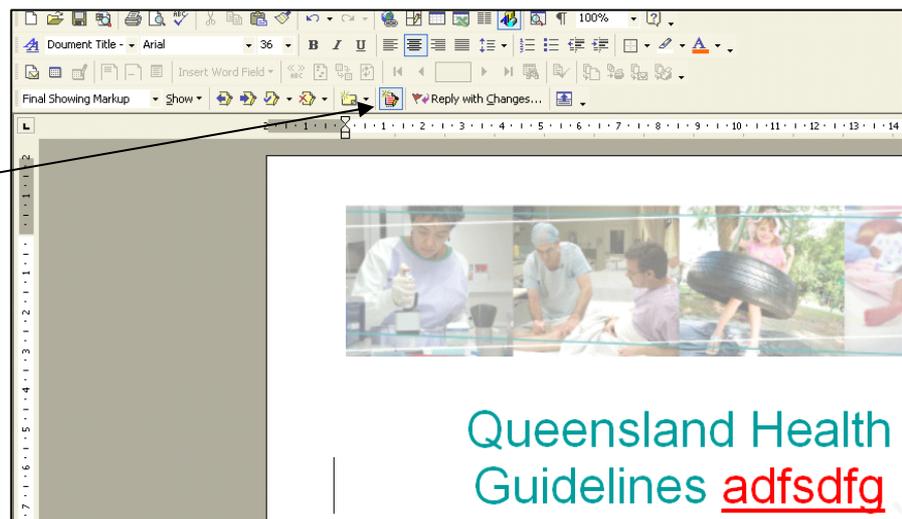
In your word document, click “File” and go down the list to “Send To” > “Mail Recipient (for Review)” and click on this option.

- An e-mail will be created with an automatically generated message requesting the recipient to review the attached document.
- The document for review will already be attached to the e-mail.
- Include any other message for the recipient.

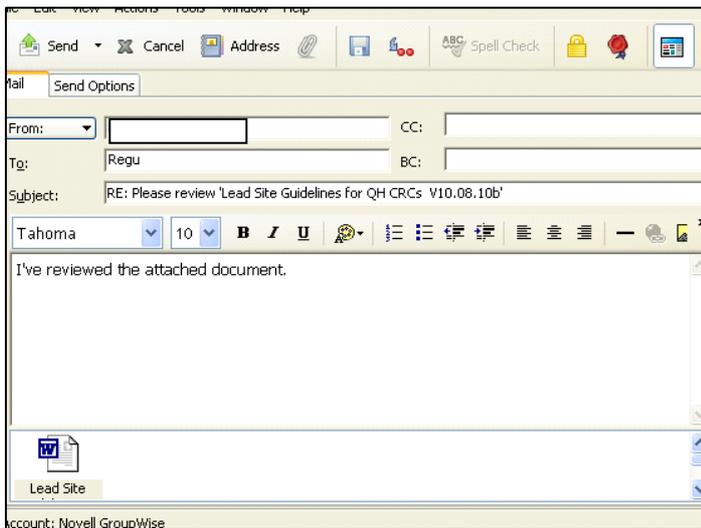


The recipient will be able to open the document and commence review and editing.

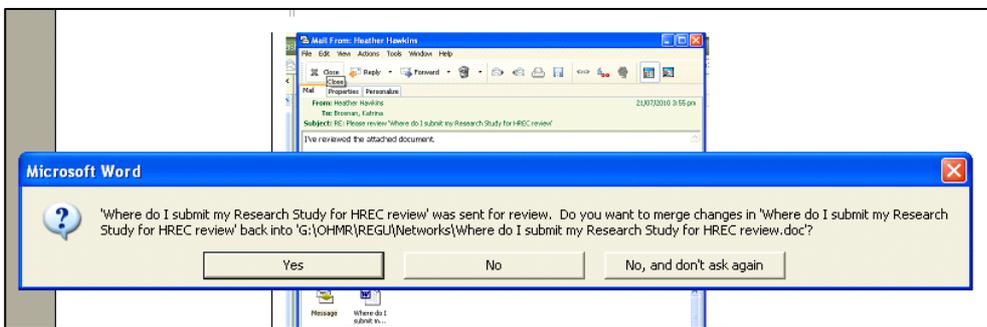
After completing the review, the recipient sends the document back to the sender by clicking on “Reply with Changes” icon on the toolbar.



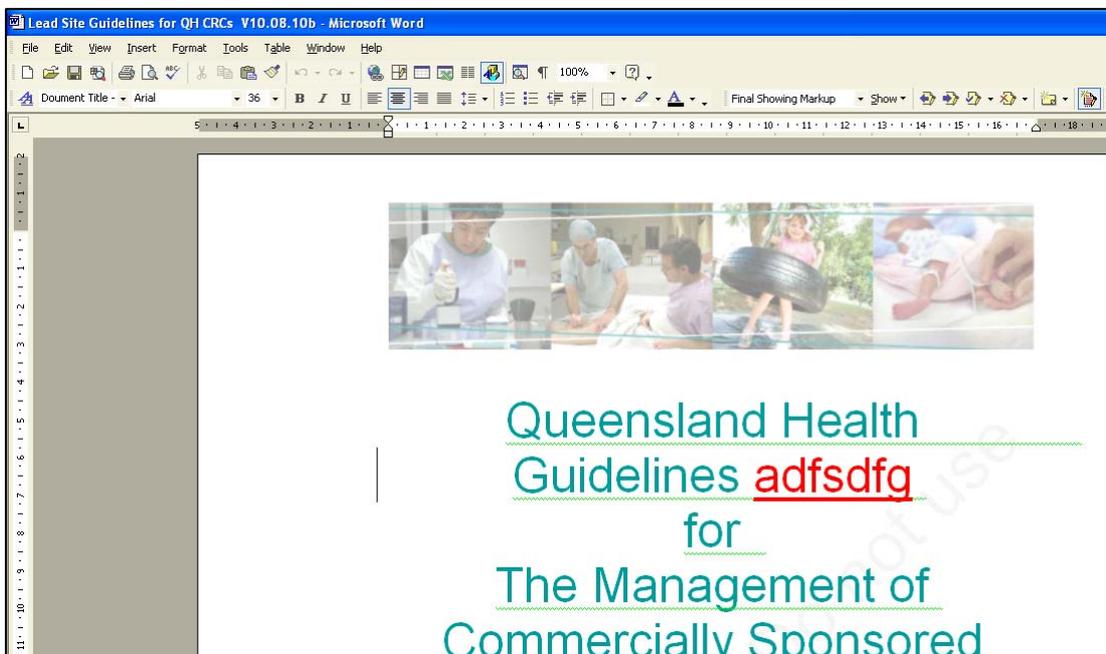
This will enable the recipient to send back to you with relevant changes and an e-mail message.



- When the reviewer sends the document back to its “owner”, the “owner” receives an e-mail with the amended document attached, and an automated message.
- When you open the attachment you will be asked if you would like to merge the changes to your original document, select whichever option suits you.



- If you select “Yes” to merge the documents you will see the amendments in the reviewed document merged into your original document, and tracked as changes.



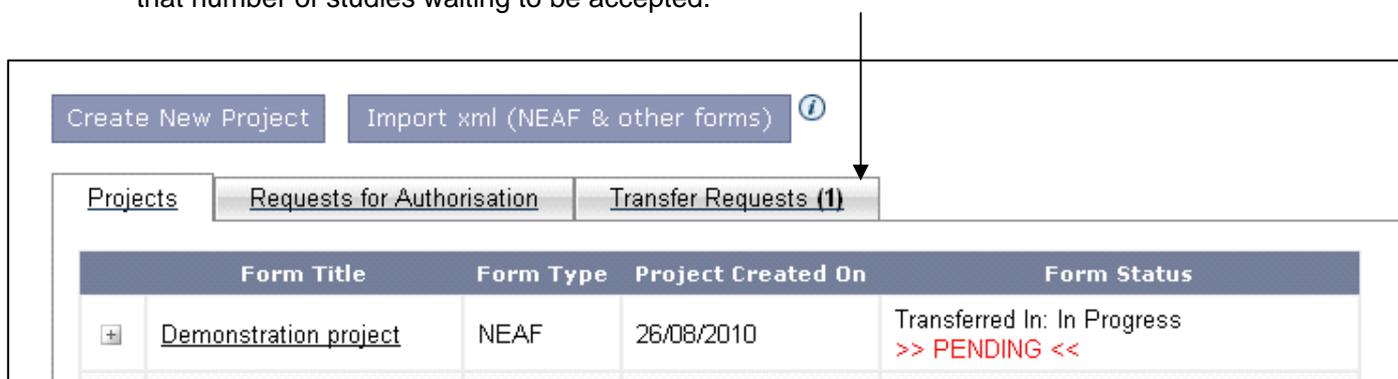
Save the document in the normal manner.

Appendix 11: Accepting an “Online Forms” document for Review

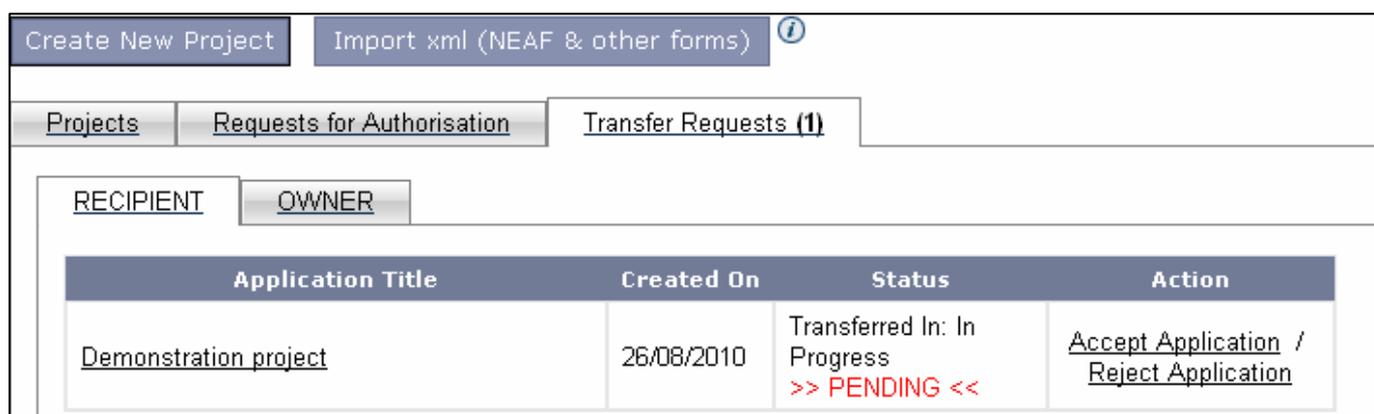
This information may be copied and e-mailed to Accepting Sites to assist them with the process of accepting an “Online Forms” document that you have sent them for review. It is best to copy and paste it into a new document and attach that document to an e-mail. If you paste it directly into an e-mail, the formatting may be lost.

How to Accept an “Online Forms” Document that has been sent to you to Review:

- You must be registered on the “Online Forms” website.
- When a document is transferred to you for review, you will receive a notification from the “Online Forms” site notifying you that you have been transferred a NEAF (or SSA Form).
- Log into the “Online Forms” site. It will open at the "My Projects" page.
- Note that the "Transfer Requests" tab will have a number in it (in brackets) indicating that you have that number of studies waiting to be accepted.



- Click on the "Transfers" tab.



- The study details will appear in a box. Go the "Action" column (right hand side)
- Click on "Accept Application". Do not click on the study name to access the document.

You now have access to the NEAF and can amend the text, save the changes Online, and upload documents in the normal manner.

To transfer the NEAF back to the Owner

- Once you have reviewed the NEAF and made any changes, click on the “Save” icon (top and bottom of each page, right hand side).
- Click on the “Navigate” icon. You will be taken to the “Index’ Screen for that project.
- Click on the “Transfer” tab.

The screenshot displays the 'Australia Online Forms for Research' web application. The header includes the logo and navigation links: HOME, MY PROJECTS, MY CONTACTS, HELP, CONTACT US, My Account, and Logout. The main content area shows a form titled 'just a test' with the following details:

- Form Type: NEAF
- Status: Transferred In: Submission Code: AU/18015/25643/1/498
- HREC Reference: None
- Owner: [Redacted]
- Form Section: N/A
- Created On: [Redacted]
- Signatures: This form is attached with electronic signatures, any changes to the form will invalidate the signatures.
- Last Modified On: 01/09/2010 13:34:55

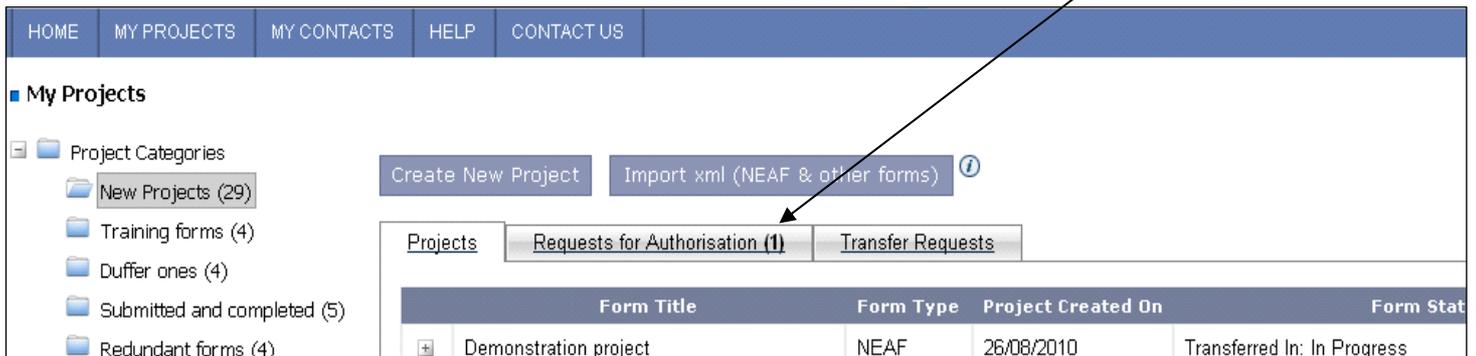
Below the form details, there is a sidebar with 'My Project' and 'NEAF' listed. The main content area has four tabs: 'Navigate', 'Documents', 'Transfer', and 'Authorisation'. The 'Transfer' tab is active, displaying a message: 'This Form has been transferred to you by [Redacted]. You may edit and print this form. You will need to get the original owner to reclaim this form to have any other action carried out such as transferring to another user.' Below the message is a text box for 'Include personal message:' and a 'Send Back Application To Owner' button labeled '>> Send Back <<'. The 'Send Back' button is highlighted in blue.

- The new screen will have a message text box in which you can type a message. When you are ready to send the NEAF back, simply click on "Send Back" and the NEAF will automatically transfer back to the owner.

Appendix 12: How to Electronically Authorise an “Online Forms” document

To electronically authorise an “Online Forms” document, you must be registered on the “Online Forms” site. You will receive an e-mail notification to the e-mail address you have nominated as your ‘log in’ e-mail, instructing you to log into the “Online Forms” site.

Once logged in, you will see on the “Requests for Authorisation” tab, that there is number in brackets, indicating the number of requests you have currently, for electronic authorisation.

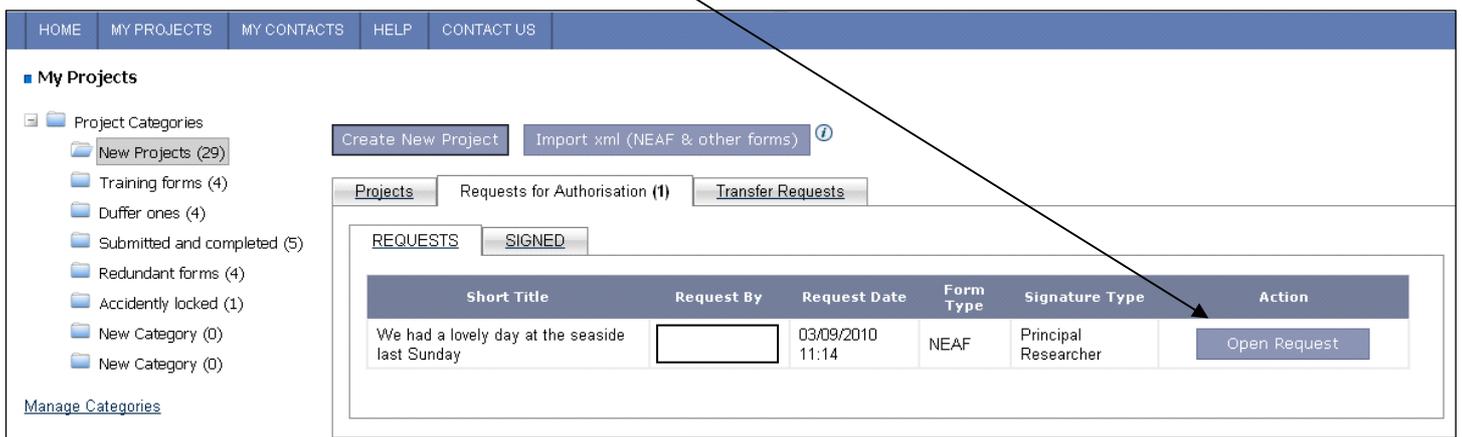


The screenshot shows the 'My Projects' dashboard. On the left, there is a sidebar with 'Project Categories' including 'New Projects (29)', 'Training forms (4)', 'Duffer ones (4)', 'Submitted and completed (5)', and 'Redundant forms (4)'. The main area has a navigation bar with 'HOME', 'MY PROJECTS', 'MY CONTACTS', 'HELP', and 'CONTACT US'. Below this, there are buttons for 'Create New Project' and 'Import xml (NEAF & other forms)'. A tabbed interface shows 'Projects', 'Requests for Authorisation (1)', and 'Transfer Requests'. The 'Requests for Authorisation (1)' tab is active, displaying a table with the following data:

| Form Title | Form Type | Project Created On | Form Stat |
|-----------------------|-----------|--------------------|-----------------------------|
| Demonstration project | NEAF | 26/08/2010 | Transferred In: In Progress |

Click on the “Requests for Authorisation” tab. The details of the study will appear in a new text box.

Do NOT open the document by clicking on the document name. Whilst this is possible, you will not be able to authorise the document if you access it in this way. The correct way to open the document is to click on the “Open Request” prompt.



The screenshot shows the 'My Projects' dashboard with the 'Requests for Authorisation (1)' tab selected. Below the navigation bar, there are buttons for 'REQUESTS' and 'SIGNED'. The 'REQUESTS' tab is active, displaying a table with the following data:

| Short Title | Request By | Request Date | Form Type | Signature Type | Action |
|--|------------|------------------|-----------|----------------------|--------------|
| We had a lovely day at the seaside last Sunday | | 03/09/2010 11:14 | NEAF | Principal Researcher | Open Request |

The next text box will prompt you to either review the form or reject the request.

Click on “Review Requested Form”. The document will open as a “Read Only” copy. Although you will be able to type text into the document, you will not be able to save any entries.

When you are ready to authorise the document, click on the “Navigate” icon (top left side of the page).

This will take you to the Index page, where the “Authorisation” tab appears.

Click on the “Authorisation” tab.

■ We had a lovely day at the seaside last Sunday

Form Type: NEAF
HREC Reference: None
Form Section: N/A
Signatures: This form is attached with electronic signatures, any changes to the form will invalidate the signatures.

Status: Submission Code: AU/1/F41707
Owner: [text box]
Created On: 24/03/2010
Last Modified On: 03/09/2010 11:13:00

My Project
NEAF

Navigate Documents Authorisation

Click [here](#) to begin completing/reviewing the form or click on the number for a specific section

Navigate by question numbers

| SECTION | QUESTION NUMBER |
|---------------------------------|-----------------------|
| 1. TITLE and SUMMARY of Project | 1-2 |
| 2. RESEARCHERS / INVESTIGATORS | 1 2 3 4 5-5c 6-7a |
| 3. RESOURCES | 1-4 5-9 |
| 4. PRIOR REVIEWS | 1-3 4-5 6-7 8-9 10 11 |

Status
 enabled disabled Page completed

The new screen will give you two options – to authorise the form, or reject the request.

■ We had a lovely day at the seaside last Sunday

Form Type: NEAF
HREC Reference: None
Form Section: N/A
Signatures: This form is attached with electronic signatures, any changes to the form will invalidate the signatures.

Status: Submission Code: AU/1/F41707
Owner: [text box]
Created On: 24/03/2010
Last Modified On: 03/09/2010 11:13:00

My Project
NEAF

Navigate Documents Authorisation

Electronic authorisations requested for this NEAF form

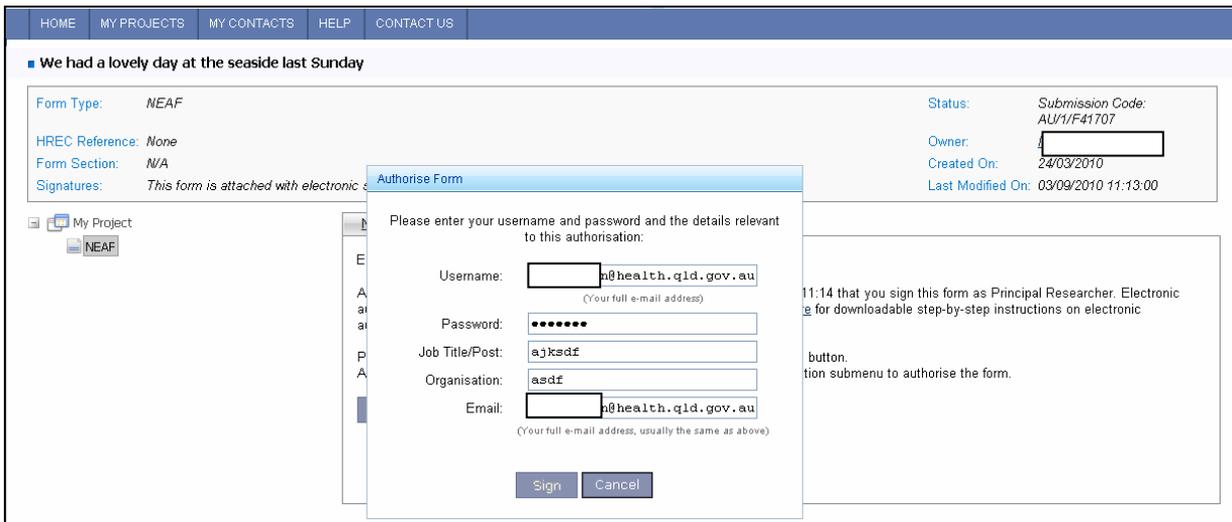
A request for authorisation was sent by [Ms Margaret Morton](#) on 03/09/2010 11:14 that you sign this form as Principal Researcher. Electronic authorisation is available as an alternative to ink signatures. Please click [here](#) for downloadable step-by-step instructions on electronic authorisations.

Please check the data in this form by clicking the "Review Requested Form" button.
After reviewing the form, click the Navigate icon and then go to the Authorisation submenu to authorise the form.

Authorise Form Reject Request

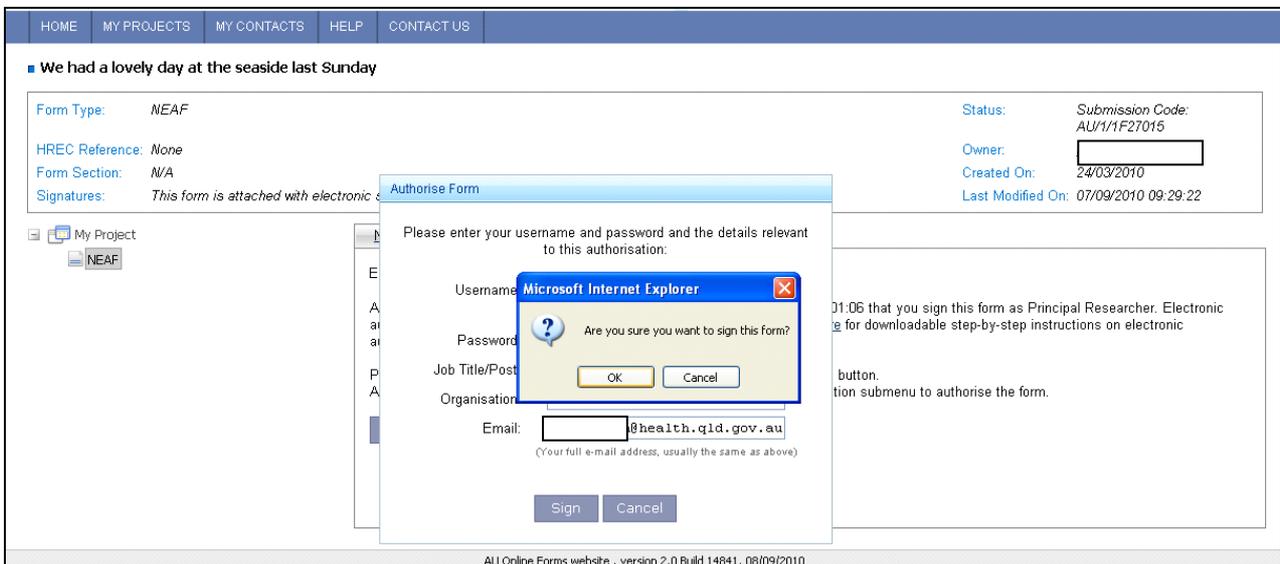
Click on “Authorise Form”.

A pop up box will appear, requesting that you insert your username (which is your log in e-mail), your password and other identifying details. Complete the text boxes and click on “Sign”.



A pop-up box will appear asking if you are sure you want to sign the form.

Click "OK"



You have now electronically signed the document. It will automatically send itself back to the owner.

Appendix 13: Summary of Submission Process for Research Studies.

Submission of multi-centre research applications to a QH HREC

International & National studies

International or National multi-centre research study being conducted at only 1 QH site

Researcher contacts QH Central Coordinating Service for allocation of the study to a QH certified HREC for ethical review

International or National multi-centre research study being conducted at more than 1 QH site

Researcher contacts QH Central Coordinating Service for allocation of the study to a QH certified HREC for ethical review

Queensland only studies

(study only being conducted within the State of Queensland)

Multi-centre research study within the jurisdictional boundaries of 1 QH District and 1 QH HREC
(e.g study being conducted at PAH, Logan & Beaudesert Hospitals)

Researcher submits directly to QH HREC in that HSD
(in example it would be to Metro South HREC)

Multi-centre research study outside the jurisdictional boundaries of 1 QH District but within the jurisdictional boundaries of 1 QH HREC
(e.g study being conducted at Townsville, Bowen & Mt Isa Hospitals)

Researcher submits directly to QH HREC
(in example it would be to Townsville HREC)

Multi-centre research study outside the jurisdictional boundaries of 1 QH District and 1 QH HREC
(e.g study being conducted at Townsville, Cairns, Gladstone & Royal Brisbane & Women's Hospitals)

Researcher contacts QH Central Coordinating Service for allocation of the study to a QH certified HREC for ethical review

For HREC jurisdictional boundaries refer to: *Where do I submit my single site research study for HREC review?* located at:
http://www.health.qld.gov.au/ohmr/documents/regu/hrec_subm_locn_sngl.pdf