Site Specific Assessment
Form Guidance

Office of Health and Medical Research
Queensland Health
June 2010
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INTRODUCTION

SSA is a component of research governance. It involves assessing the suitability of a site at which the research is being conducted and identifying whether the ‘actual’ and or ‘in kind’ resources required for the conduct and completion of the project are being met by the sponsor or can be met by the District.

The SSA is the mechanism for financial accountability and transparency and is consistent with the NHMRC Code of Responsible Conduct of Research (2007) and the requirements of the Queensland Government Financial Accountability Act 2009. It is also the mechanism used to assist Queensland Health (QH) Districts and sites to identify and quantify the contribution of resources and assist in future operational planning and budgets. The QH Research Management Policy and Framework 2008 / 2010 provides further information and guidance for researchers.

Human Research Ethics Committee (HREC) approval of the research protocol is a pre-requisite for submission of a SSA at the research site. Final approval to conduct a study at a site requires:

- consideration and sign off on the financial commitment by the Director of Finance or delegate, Heads of Department at the District/site where there are resource demands; and
- the District CEO or Delegate to provide final authorisation on the provision of resources at the District/site where the research is being conducted.

The SSA form must be completed by the local site Principal Investigator or Site Coordinator responsible for the research project at the site at which the research is being conducted. Not all sections of the form will be relevant. However it is important that where there is funding or resources associated with the project – these costs/resources are identified and quantified.

Negotiations with the relevant Heads of Departments and Director of Finance should commence and run parallel to the HREC approval cycle. However, researchers should not submit their completed SSA Form to the RGO until the protocol has received HREC approval. HREC approval is not authorisation to commence research.

All relevant aspects of the SSA form are to be completed and the required associated documents attached. All supporting documentation should also be uploaded on the online forms website.

The SSA form is to be forwarded to the District/site Research Governance Office (RGO) at the site of the research for consideration and checking prior to final Authorisation by the District CEO or Delegate. Refer to: http://www.health.qld.gov.au/ohmr/html/regu/for_researcher.asp for Research Governance contact details.

SSA Forms are generated from the NEAF ‘Action Tab’. Refer to the Online Forms Manual for guidance on generating an SSA: https://ethicsform.org/Au/Help/AU%20Online%20Forms%20for%20Research%20User%20Manual%20v1.2.pdf

Parts of the SSA form will be automatically populated with information from the online National Ethics Application Form (NEAF). Researchers are given the option to ‘override’ automatically populated from the NEAF by ‘unticking’ the tick box which states ‘Automatically populate from NEAF’. This allows the researcher to enter site specific details which may be different from the details on the NEAF. Where this does not occur, researchers will need to complete the details manually.
SITE SPECIFIC ASSESSMENT FORM COMPLETION

1. Project Details

1.1 Purpose
The provision of this information enables the QH site RGO to liaise with the reviewing HREC and register the completed SSA in the Australian Research Ethics Database (AU-RED). Investigators should register a SSA on-line through the NEAF portal using the QH on-line form website: http://www.ethicsform.org/au/SignIn.aspx.

If the NEAF has been created using the NHMRC version of the form, it must be imported into the AU-RED compatible version, in order for a SSA Form to be generated. See QH Researcher User Guide for instructions: http://www.health.qld.gov.au/ohmr/documents/researcher_userguide.pdf or the Online Forms Manual: https://ethicsform.org/Au/Help/AU%20Online%20Forms%20for%20Research%20User%20Manual%20v1.2.pdf

1.2 Specific Guidance
The information pertaining to the “Title”, of the study will be automatically populated from NEAF.

The HREC application reference number must be completed if it has not auto populated from the NEAF.

For multi-centre research, a separate SSA must be completed for each site at which the research is to be conducted. The investigator should list only the site to which the SSA relates.

2. Description of Project in Plain Language

2.1 Purpose
The provision of this information enables the site RGO to readily ascertain the nature of the research project and its possible implications for the site.

2.2 Specific Guidance
This information will be automatically populated from the NEAF.

3. Study Type, NHMRC Group and Fields of Research

3.1 Purpose
The provision of this information allows for District reporting of the annual report to Chief Scientist.

3.2 Specific Guidance

Study Type:
The study type is used to enable searches of study types to be performed in AU RED. It should be categorised in the following order:

- First time in human clinical trial / first time in patient clinical trial
- Clinical trial of a drug / device
- Clinical research (includes all other clinical research and clinical trials not involving drugs / devices)
- Health research / social sciences
- Other
NHMRC group
A research project or research program should be allocated to a single type of activity. If the project or program is large and involves multiple types of activity, then main relevant activity category should be identified.

NHMRC Field of Research
This information reflects disease and health issues that are relevant to the NHMRC Strategic Plan. It can also be used to enable districts to search on research being conducted in disease priority areas and enable searches of categories to be performed in AU RED.

4. Research Personnel

4.1 Purpose
The provision of this information identifies the key personnel and contacts.

4.2 Specific Guidance
This section relates to the researchers involved in the project at the site. A current CV (2 page maximum) must be provided for each researcher involved in the project. If the site already has a copy of the CV on file, the researcher may not need to submit another copy; however this should be confirmed with the site.

Each site should have only one Principal Investigator (PI). The PI is responsible for the conduct of the research at the site. All other researchers should be recorded as Associate Investigators.

The easiest way to enter researchers into Section 4 is to go to "My Contacts" on the top of the SSA page. Create a contact for each of the researchers associated with the project (include the researcher’s own details). Then in the SSA Form, when details of researchers are requested, simply click on the icon (which looks like a letter box or a book with a bookmark) and this will take the researcher to the Contact List. Select one person at a time from the list, click on "View" and check that the contact details are correct. Then click on "Copy Details into the Form". The contact details will upload into the form. The Contact List is attached to the researcher’s account, not to the application, so the list can be used for all subsequent applications.

5. Training

5.1 Purpose
The provision of this information enables the RGO to consider whether extra research training is necessary to fulfil the researcher roles in the research project and identify who will provide the training.

5.2 Specific Guidance
The Principal Investigator /Site Investigator will need to complete the information for those sections that are not covered by the NEAF. The investigator should list only the training needs for the site to which the SSA relates.
6. Recruitment

6.1 Purpose
The provision of this information enables the RGO to consider whether the process to identify potential eligible research participants for the study at the site complies with State privacy legislation, local site requirements and QH policies and guidelines.

6.2 Specific Guidance
Sections 6.1, 6.2 and 6.4 will automatically populate from the NEAF.

6.1 The investigator should describe how potentially eligible participants will be identified at the site. The process for identifying possible research participants for the study must comply with the States’ information releases and research provisions.

6.2 The investigator should describe the recruitment contact process for the site

6.3 The investigator should identify the probable number of research participants for the site to which the SSA relates.

6.4 The investigator should identify the probable categories/participant group/s that will be recruited for the site to which the SSA relates. For example, the site will consider the extent to which the proposed targeted participant group has been involved in other research projects, to ensure there is not an unfair burden of participation in research on that particular group. All participant boxes should be completed.

7. Anticipated start and finish dates for the research project

7.1 Purpose
The provision of this information enables the RGO to consider whether the requested use of facilities, staff and resources will be available and whether it is appropriate to allow the research project to commence at this site, given the expected commencement and duration of the research project.

7.2 Specific Guidance
Section 7 will automatically populate from the NEAF. However, these dates may be altered to accommodate different start up dates site to site.

8. QH policy on access to confidential information held by the department

8.1 Purpose
The provision of this information enables the RGO to ensure that access to confidential health information held by QH has the approval of the data custodian and meets the research requirements under s281 of the Public Health Act 2005.


8.2 Specific Guidance
Information on how to obtain Director-General approval to access QH confidential health information under the Public Health Act 2005 research provisions may be found on the QH Research Ethics and Governance Unit website. Application process and forms are available on this site: http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp
9. Research Using Information or Resources of Clinical and Statewide Services (CaSS)

9.1 Purpose
Authorisation to Proceed from the Chief Executive Officer CaSS is required for any research project using information for which CaSS (including Pathology Queensland, Forensic and Scientific Services, Medication Services Queensland and other branches of CaSS) is the data custodian and for any research project involving CaSS staff or resources. This includes but is not limited to:

- Research projects using Pathology Queensland samples
- Clinical trials that require access to archived data and samples
- Clinical trials involving access to the resources of central pharmacy

The CaSS Coordination Planning and Research Unit (CPRU) is responsible for managing CaSS approval process and will assist researchers with this process.

For use of human tissue that is held by Queensland Health – Contact Research Office in Clinical and State-wide Services or visit: http://www.health.qld.gov.au/qhcss/research/info.asp

For all research projects undertaken using resources held by Clinical and State-wide Services (CaSS) (facilities and tissue samples), researchers must make application to the CaSS Research Committee after HREC approval has been given: http://www.health.qld.gov.au/qhcss/research/info.asp

9.2 Specific Guidance
Information on how to obtain approval to access and use human tissue and facilities from CaSS can be found by contacting the CaSS Research Officer on 07 3636 9865

10. Research involving access to coronial material

10.1 Purpose
Research involving access to coronial material must be referred to the Queensland Health Forensic and Scientific Services Human Ethics Committee (FSS-HEC) for ethical and legal approvals. This also applies to clinical research projects where there is a component involving coronial material. In this context, examples of coronial material include tissues from coronial autopsies, slides and blocks, blood samples, autopsy reports and other documents and data relating to coronial autopsies. Information on the Forensic and Scientific Services can be obtained from: http://www.health.qld.gov.au/qhcss/qhss/default.asp


The provision of this information enables the RGO to determine if the correct ethical approval processes have been followed

10.2 Specific Guidance
Research involving access to coronial material must have been approved by the QH Forensic and Scientific Human Ethics Committee and received approval from the State Corner to conduct the research.
11. Research involving adults with impaired capacity to consent

11.1 Purpose
Where a person is over the legal age of consent but is unable to give consent, written application to the Queensland Civil and Administrative Tribunal (QCAT) must be undertaken. For further information please to the Queensland Civil and Administrative Tribunal:

The provision of this information enables the RGO to determine if the correct ethical approval processes have been followed

11.2 Specific Guidance
Where a person is over the legal age of consent but is unable to give consent a written application to the Queensland Civil and Administrative Tribunal (QCAT) must be undertaken.

12. Research involving Aboriginal and Torres Strait Islander peoples including coincidental recruitment

12.1 Purpose
Applicants should address the extent to which their application fulfils the following criteria in relation to research into the health of Indigenous Australians including documentation and other relevant written evidence where appropriate. The criteria are: Reciprocity and community engagement; Respect; Equality; Responsibility; Survival and protection; and Spirit and integrity.


The provision of this information enables the RGO to identify if the relevant engagement with Aboriginal and Torres Strait Islander communities, relevant to the site, has occurred.

12.2 Specific Guidance
Researchers need to identify that they have consulted with the relevant Aboriginal and Torres Strait Islander communities.

13. Clinical Trials

13.1 Purpose
The provision of this information and relevant documentation allows for relevant institution sign off.

13.2 Specific Guidance
Section 13 will only appear on the SSA Form if Section 5 Question 1 ‘Clinical Research’ has been selected on the NEAF

13.1 The researcher should identify which Phase of the study is being conducted. If the study covers more than one Phase select the most applicable phase.
13.2 Some types (both commercially sponsored and non commercially sponsored) of research projects involve unapproved therapeutic goods and require regulation under the Therapeutic Goods Act 1989 (both CTN and CTX schemes). Further information on both the CTN and CTX schemes and completion of CTN / CTX is available on:  http://www.tga.gov.au/ct/index.htm

Section 13.2 will automatically populate from the NEAF.

13.3 Section 19 of the Declaration of Helsinki (2008) states: “Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject”. In addition, the International Committee of Medical Journal Editors (ICMJE) has made an essential criterion for publication of a trial in one of their journals that the details of a trial should be publicly available in a clinical trials registry. Researchers need to justify why the trial is not registered on a trial database.

14. Clinical Studies – indemnity and insurance

14.1 Purpose
The provision of this information (insurance and indemnity documents) enables the RGO to assess whether the required insurance and indemnity provisions are adequate

14.2 Specific Guidance
If a standard MA CTA is used, insurance and indemnity arrangements are also covered in Schedule 3 & 4 of the CTA. For sponsored studies, the researcher should also supply the certificate of insurance to the RGO.

The Medicines Australia Standard Indemnity Form referred to in this section is available at: http://www.medicinesaustralia.com.au/pages/images/Form%20of%20Indemnity.doc

The Medicines Australia Form of Indemnity – HREC Review only is available at: http://www.medicinesaustralia.com.au/pages/images/Form%20of%20Indemnity%20HREC%20Onl y%20version%2020230507B.doc

15. Research Study Agreements

15.1 Purpose
Clinical study agreements describe the terms and conditions of conducting a study, including roles and responsibilities of stakeholders, payments, indemnity, insurance and compensation.

15.2 Specific Guidance
Industry sponsored studies CTA:
For industry sponsored studies where the company has accepted all the roles of the sponsor the Medicines Australia Standard Clinical Trial Agreement should be used: http://www.medicinesaustralia.com.au/pages/images/Standard-Clinical-Trials-Research-Agreement-Commercially-Sponsored-Trials.doc

Contract Research Organisation (CRO) CTA:
In the case of a Contract Research Organisation (CRO) sponsored clinical trial, where the CRO has accepted all the roles of the sponsor the Standard Clinical Trial Research Agreement for Contract Research Organisations should be used: http://www.medicinesaustralia.com.au/pages/images/Standard-Clinical-Trial-Research-Agreement-for-Contract-Research-Organisations.doc
Collaborative Sponsored CTA:
In the case of a collaborative sponsored clinical trial, the Standard Clinical Trial Agreement for Collaborative or Cooperative Research Group (CRG) Studies should be used:

Industry Sponsored Device Trial CTA:
For industry sponsored device trials the Standard Industry Sponsored Device Clinical Trial Agreement should be used:

Post marketing surveillance study CSA:
For Post marketing surveillance / Phase IV studies the QH Standard Post marketing surveillance / Phase IV studies Agreement should be used.

Investigator Initiated Clinical Trial CTA:
For Investigator Initiated Clinical Trials the QH Standard Investigator Initiated Clinical Trial CTA should be used.

Where companies use the standard agreements without alteration, QH should accept these agreements without further legal review

Other CA
All other non standard Clinical Agreements not approved for use by QH e.g. other investigator initiated research, co-joint researchers, and students - non clinical research will need review by the District Health Services Lawyer or QH approved legal panel firm.

If a sponsor wishes to use their own (non approved) contract, or have amendments made to a standard MA CTA, a written undertaking should be obtained from the sponsor to pay for any legal fees incurred by Queensland Health for review of the non-standard contract.

The parties to a contract need to be properly identified to ensure that the correct legal entity is bound by the contract.

Parties to a contract
The 'State of Queensland' is the contracting party for all QH agreements. The various state government departments (including QH) are not separate legal entities and cannot enter into contracts. Any wording which follows "The State of Queensland" is descriptive only and intended to assist the parties in identifying the relevant part/area/department within the State involved in the contract.

QH should be described on all research contracts as: "The State of Queensland acting through Queensland Health (name of hospital/district) of (Address of Institution)".
16. Intellectual property considerations

16.1 Purpose
The provision of this information enables the RGO to consider whether the intellectual property arrangements for the research project are consistent with QH Intellectual Property Policy.

16.2 Specific Guidance

The Queensland Health Intellectual Property policy covers the following:

- Identification and contractual arrangements for the use and ownership of new and existing intellectual property that may be developed through the research project.
- If there is a possibility of new Intellectual Property being developed from this project and the contract does not state arrangements for the use of existing intellectual property and the parties’ rights in relation to ownership and use of all new intellectual property developed through the research then following steps should be taken:
  (i) Discuss the issue of incorporating intellectual property terms in the contract with the researcher’s associates and any legal or business manager assisting with development of the contract; and
  (ii) Contact the Intellectual Property Unit within the Office of Health and Medical Research by emailing ip_officer@health.qld.gov.au to determine if the terms are suitable for Queensland

17. Biosafety, chemical and radiation safety

17.1 Purpose
To enable the RGO to ensure that biosafety, drug committee and radiation safety approvals have been obtained where necessary.

17.2 Specific Guidance
Some types of research projects (such as research involving gene therapy), necessitate review and/or approval by an Institutional Biosafety Committee (IBC), and the NHMRC Cellular Therapies Advisory Committee (CTAC). Contact the HREC for details of the relevant IBC.

Contact the Cellular Therapies Advisory Committee at: http://www.nhmrc.gov.au/about/committees/expert/ctac/index.htm

Where a project requires compliance with the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code, a physicist report will be required. Section 2.1.6 of the ARPANSA Code on Exposure of Humans to Ionizing Radiation for Research states that a researcher must obtain an independent assessment or verification by a Medical Physicist. Contact details for radiation safety licensed persons can be accessed at: http://www.health.qld.gov.au/radiationhealth/default.asp
18. Resources and Budget Information

Section 18.1: Departments & services involved in the research

18.1 Purpose
The provision of this information enables the RGO to consider whether the department and services involved in the research are identified and the Head of Department has been involved in any negotiations.

18.2 Specific Guidance
Researchers should have a signed declaration from the Head of Department or Services area where resources are required, prior to submission of the SSA. It is highly recommended that researchers (and sponsors if applicable) contact the relevant supporting departments within an institution (eg Pathology, Pharmacy, Radiology, Allied Health etc) prior to HREC submission, to ensure that the services / samples etc, can be provided by the department.

Section 18.2: Study Budget at the Site

18.2.1 Purpose
The provision of this information enables the QH site to identify the essential source of funding for a research project and the annual or participants cost associated with the study. This also provides data for the annual QH Chief Scientist report.

18.2.2 Specific Guidance
Information should be as accurate as possible, identifying the type, source and amount of funding being made available.

Section 18.3: Site Finance Management

18.3.1 Purpose
The provision of this information enables the QH site to identify if all research costs are covered by the sponsor or if not covered how the institute will benefit from the non funded research, and from which cost centre those costs will be recovered.

18.3.2 Specific Guidance:
Information should be as accurate as possible, identifying the breakdown of the study budget.

Section 18.4: Finance Authorisation

18.4.1 Purpose:
The provision of this information enables the RGO and site Finance Director or delegate to identify, determine and authorise any 'in kind' support and or resources for the conduct and completion of research at that site. This requirement is consistent with the obligations of financial management under the Financial Management Standard 1997.

18.4.2 Specific Guidance:
Where there are resource demands for a QH facility department – the researcher is to discuss what the funding and resource requirements are and cost these accordingly. The Director of Finance or delegate must sight and consider the implications for the site budget before giving authorisation.
19. Funds management

19.1 Purpose
The provision of this information enables the RGO to streamline its financial accounting processes in line with the Financial Management Standard 1997.

19.2 Specific Guidance:
Provide details of the designated Queensland Health Cost Centre and or Internal order number when the funding for the project is being managed by the Department. Where funds are being managed from another site e.g. university, cost centre or account name is required so when invoicing the organisation in order to recoup cost, – reference may be made to the specific account.

20. Database of Research Activity (DORA)

20.1 Purpose
The Database of Research Activity is a publicly accessible, searchable internet web site which takes an automatic download of research data from the AU-RED system and presents it in a format to allow researchers and other interested public stakeholders to search for and view summary level information about research being conducted in Queensland Health.

The searchable database covers all Queensland Health human research (not just clinical trials) and is designed to facilitate greater collaboration and communication between researchers, improve patients' access to research information and raise awareness about the benefits of health and medical research.

20.2 Specific Guidance
Sections 20.1 – 20.10 will be auto populated from previous sections of the SSA Form. Researchers will be asked if they have the authority to consent for the release of the data and if so, give consent for the release of the data. The Research Ethics and Governance Unit will follow up those researchers who do not consent for the data to be released for DORA.

21. Declarations

Section 21a: Declarations from investigators and site coordinator

21.1a Purpose:
The provision of this information enables the RGO and or delegate to determine if all the researchers and site coordinator are aware of their roles and responsibilities in regards to the conduct and completion of research at the site.

If an investigator will not be available to sign this page after the SSA form is locked (eg will be on leave), a signed letter from the Investigator stating that they are familiar with the protocol and are able to fulfil all requirements for the conduct of the study is sufficient and should be inserted into the hard copy of the form, and where possible, scanned and electronically uploaded and attached to the application.
Section 12.1b: Declarations from Head of Department or delegate where the research project will be conducted

21.1b Purpose:
The provision of this information enables the RGO to determining if the research is supported within an institution.

If the Head of Department will not be available to sign this page after the SSA form is locked (eg. will be on leave), they may nominate a delegate to sign, or they may sign a statement of support for the project and this should be inserted into the hard copy of the form, and where possible, scanned and electronically uploaded and attached to the application.

Section 21c: Declarations from Head of Department or delegate providing support and/or services to the research project

21.1c Purpose:
The provision of this information enables the RGO to determine under what conditions institutional departments can provide support for the research project. It is highly recommended that researchers contact the relevant supporting departments within an institution (eg. Pathology, Pharmacy, Radiology, Allied Health etc) prior to HREC submission, to ensure that the services, can be provided by the department.

If necessary, this page to be photocopied to enable Declarations from various Heads of Departments.

If the Head of Department will not be available to sign this page after the SSA form is locked (eg. will be on leave), they may nominate a delegate to sign, or they may sign a statement of support for the project and this should be inserted into the hard copy of the form, and where possible, scanned and electronically uploaded and attached to the application.
QUEENSLAND HEALTH

Appendix A: Site-Specific Assessment (SSA) Form – Clinical Trial Example

SSA is a component of research governance. It involves assessing the suitability of a site at which the research is being conducted and identifying whether the ‘actual’ and or ‘in kind’ resources required for the conduct and completion of the project can be met by the District. The SSA is the mechanism for financial accountability and transparency and is consistent with the Queensland Government Financial Accountability Act 2009. It is also a means by which Districts may quantify the contribution made by Queensland Health and manage and plan budgets.

Human Research Ethics Committee (HREC) approval of the research protocol is a pre-requisite for submission of an SSA at the research site. Final approval to conduct a study at a site requires:

- consideration and sign off of the financial commitment by the Director of Finance or delegate at the District/site; and
- the delegated District CEO or delegate to provide final sign off on the provision of resources at the site where the research is being conducted.

INSTRUCTIONS FOR THE PRINCIPAL INVESTIGATOR

- This form must be completed by the local site Principal Investigator or delegate where the research is being conducted. Not all sections of the form will be relevant.

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

- The SSA form must be forwarded to the District/site research governance personnel at the site of the research for consideration and checking prior to final Authorisation by the District CEO or delegate.

- All aspects of this SSA form are to be completed where relevant and the required associated documents attached.

- The checklist on the back of the SSA form will assist to ensure a full submission is completed before forwarding to the District/site research governance personnel at the site.

Limited information on this SSA has been populated from your final approved ethics application form. Please complete all sections that are relevant to the study and site at which the study is to be conducted.
1. Project details

HREC Application Reference Number: HREC/10/QPAH/654
Name of HREC reviewing the research project: Princess Alexandra Hospital Human Research Ethics Committee (Automatically populated from NEAF)
Give the name of the project site to which this SSA applies: Princess Alexandra Hospital, Qld
Single site study  □  Multicentre study  X
Title (in full): APRICOT: A Phase 3 Multicenter, Randomized, Placebo-Controlled, Double-Blind Twelve-Month Safety and Efficacy Study Evaluating XXXC in Patients with KKKK Disease who are receiving standard therapy. Protocol No: KMB987456 (Automatically populated from NEAF)
Short title: “The safety and efficacy of XXXC in patients with KKKK disease who are on standard therapy”. (Automatically populated from NEAF)
Acronym: “APRICOT”

2. Description of the Project in Plain Language

Give a concise and simple description (not more then 400 words), in plain language, of the aims of this project, the proposal research design and the methods to be used achieve those aims).

KKKK Disease is a disease which affects brain processes. The current medications available to treat this disease are limited. Thus, there is a need for new therapies with greater efficacy and/or effects on the rate of disease progression.

This study evaluates the safety and efficacy of XXXC in combination with standard therapy. This study will determine whether XXXC (study drug) combined with standard therapy improves the symptoms of KKKK disease. The study will evaluate two doses of oral KKKK (16 mg three times a day and 8 mg three times a day) administered for 12 months (52 weeks). The other countries participating in the study include New Zealand, Canada and the United States.

Approximately 1,050 patients will be centrally allocated into three groups of 350 patients each: XXXC 16 mg three times a day; XXXC 8 mg three times a day; and placebo. Standard therapy will be supplied as a study medication for all patients on the study.

The study is open to both males and females aged 50 year or older who have KKKK disease.

Participants will attend the clinic a total of 10 times and each visit should last about 3 hours. During these visits participants will be required to complete a number of questionnaires and tests to assess different brain functions.

A blood sample will be collected at the baseline visit to perform genetic blood tests. Pharmacogenetics is the study of how our genetic make-up affects how our bodies react to or handle medications. If it appears that there is a difference in patients’ responses to XXXC, the sponsor may study these differences using genetic material taken from these blood samples.

Safety and tolerability will be assessed by recording of adverse events and by monitoring of vital signs, physical examinations, safety laboratory evaluations, and 12-lead electrocardiograms (ECGs). An independent Data Monitoring Committee will monitor safety data in the trial on an ongoing basis.
3. Study type and NHMRC Group and Field of Research

3.1 Please select study type (one only) Mandatory field

<table>
<thead>
<tr>
<th>Study Type</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Research</td>
<td></td>
</tr>
<tr>
<td>Clinical trial of a drug</td>
<td>X</td>
</tr>
<tr>
<td>Clinical trial of a device</td>
<td></td>
</tr>
<tr>
<td>Other clinical trial</td>
<td></td>
</tr>
<tr>
<td>First time in human clinical trial / First time in patient clinical trial</td>
<td></td>
</tr>
<tr>
<td>Health research / Social science</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

3.2 Please select the NHMRC Group and sub Field of Research from the drop down boxes.

The appropriate item is to be selected from the drop down boxes. These are mandatory fields and the SSA can not be progressed until these fields are completed. Mandatory fields
### 4. Researcher(s)

Provide details of researchers at this site:

#### 4.1 Principal Investigator(s) NEAF 2.1

(Use the ‘mailbox’ icon linked to the contacts list to enter the contact details more quickly)

<table>
<thead>
<tr>
<th>Title:</th>
<th>Dr</th>
</tr>
</thead>
<tbody>
<tr>
<td>First name:</td>
<td>Johnathon</td>
</tr>
<tr>
<td>Surname:</td>
<td>Smithers</td>
</tr>
<tr>
<td>Mailing address:</td>
<td>C/- Neurology Department, The General Hospital</td>
</tr>
<tr>
<td>Suburb/Town:</td>
<td>Brandenville</td>
</tr>
<tr>
<td>State:</td>
<td>Queensland</td>
</tr>
<tr>
<td>Post code:</td>
<td>4111</td>
</tr>
<tr>
<td>Country, if not Australia:</td>
<td></td>
</tr>
<tr>
<td>Organisation Name:</td>
<td>The General Hospital</td>
</tr>
<tr>
<td>Position in organisation:</td>
<td>Neurologist</td>
</tr>
<tr>
<td>Business hours phone number:</td>
<td>+ 61 7 1234 5678</td>
</tr>
<tr>
<td>Fax number:</td>
<td>+ 61 7 8765 4321</td>
</tr>
<tr>
<td>Email address:</td>
<td><a href="mailto:Johnathon.smithers@brains.com.au">Johnathon.smithers@brains.com.au</a></td>
</tr>
</tbody>
</table>

**Medical Staff only:**
- Have you been credentialed at a Queensland Health District? Yes ✓
- What is the expiry date? 30.06.2012
- Does the credentialing scope of clinical practice cover all the relevant aspects of the investigator’s participation in this study? Yes ✓

*For some research studies the local site PI may be the Coordinating PI. For all studies there must be an onsite contact person.*

---

#### 4.2 Associate Investigator(s)

Add as many Associate Investigators as required for this site

(Use the ‘mailbox’ icon linked to the contacts list to enter the contact details more quickly)

<table>
<thead>
<tr>
<th>Title:</th>
<th>Dr</th>
</tr>
</thead>
<tbody>
<tr>
<td>First name:</td>
<td>Miriam</td>
</tr>
<tr>
<td>Surname:</td>
<td>Thomas</td>
</tr>
<tr>
<td>Mailing address:</td>
<td>C/- Neurology Department, The General Hospital</td>
</tr>
<tr>
<td>Suburb/Town:</td>
<td>Brandenville</td>
</tr>
<tr>
<td>State:</td>
<td>Queensland</td>
</tr>
<tr>
<td>Post code:</td>
<td>4111</td>
</tr>
<tr>
<td>Country, if not Australia:</td>
<td></td>
</tr>
<tr>
<td>Organisation Name:</td>
<td>The General Hospital</td>
</tr>
<tr>
<td>Position in organisation:</td>
<td>Neurologist</td>
</tr>
<tr>
<td>Business hours phone number:</td>
<td>+ 61 7 1234 5678</td>
</tr>
<tr>
<td>Fax number:</td>
<td>+ 61 7 8765 4321</td>
</tr>
<tr>
<td>Email address:</td>
<td><a href="mailto:Miriam.Thomas@brains.com.au">Miriam.Thomas@brains.com.au</a></td>
</tr>
</tbody>
</table>

**Medical Staff only:**
- Have you been credentialed at a Queensland Health District? Yes ✓
- What is the expiry date? 30.06.2012
- Does the credentialing scope of clinical practice cover all the relevant aspects of the investigator’s participation in this study? Yes ✓
4.3 * Contact person at this site for this research project

(Use the ‘mailbox’ icon linked to the contacts list to enter the contact details more quickly)

Title: Ms
First name: Helen
Surname: White
Mailing address: C/- Neurology Department, The General Hospital
Suburb/Town: Brandenville
State: Queensland
Post code: 4111
Organisation Name: The General Hospital
Position in organisation: Research Manager, Study Coordinator
Business hours phone number: + 61 7 1234 8765
Fax number: + 61 7 8765 4321
Email address: Helen.White@brains.com.au

* The PI will be responsible for ensuring there is a Contact Person at the site who will liaise with the District/site research governance personnel. The contact person may be the PI or a person nominated by the PI however they must be located at the site.
5. Training

Will any of the researchers at this site require extra training to enable their participation in this project? Yes

If Yes, list the researchers, describe the training that is required and who will provide this training – at this site.

<table>
<thead>
<tr>
<th>Researcher</th>
<th>Training required</th>
<th>Who will provide training</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Johnathon Smithers</td>
<td>Information about the Investigational product, study protocol, procedures and assessments</td>
<td>Sponsor company at the Investigator Meeting</td>
</tr>
<tr>
<td>Dr Miriam Thomas</td>
<td>Information about the Investigational product, study protocol, procedures and assessments</td>
<td>Sponsor company at the Investigator Meeting</td>
</tr>
<tr>
<td>Ms Helen White</td>
<td>Information about the Investigational product, study protocol, procedures and assessments</td>
<td>Sponsor company at the Investigator Meeting</td>
</tr>
</tbody>
</table>

6. Recruitment

6.1 Recruitment process (Automatically populated from NEAF)

What process will be used to identify potential participants for the study at this site?

Patients will be identified from those referred to Neurology clinics at the site, and from perusal of the Investigators records of previous patients.

6.2 Recruitment at the site (Automatically populated from NEAF)

Describe how initial contact will be made with potential participants at this site.

Patients who are identified as possible participants (by the Investigators) will be telephoned by the study coordinator, who will discuss the research project with the patients. If they indicate an interest in participating, and if they broadly meet the Inclusion/exclusion criteria, the Participant Information Sheet and Consent form will be posted out to them. The study coordinator will follow-up after one week, and if the patients are interested in participating, a screening visit will be scheduled.

6.3 How many Participants at this site

What is the proposed number of participants to be recruited?

6 - 10
6.4 Participant details

What categories of people will be recruited at this site? (e.g. children and young people, people with an intellectual or mental impairment, people highly dependent on medical care, people in dependent or unequal relationships, Aboriginal & Torres Strait Islander people, persons in custody, etc).

Automatically populated from NEAF with ability to over write text

7. Provide the anticipated start and finish dates for the research project at this site.

7.1 Start date * 12/12/2010
7.2 Finish date # 12/12/2014
7.3 Durations (months): 48 months

* Start date refers to the anticipated first point of recruitment i.e. the date when the advertising or screening for participants begins.

# Finish date refers to when no further contact with participants/data source is foreseen including the data analysis and reporting period.

8. Queensland Health policy on access to confidential information held by the Department.

All studies
8.1 Have you consulted with the data custodian/s regarding access to Confidential Information held by Queensland Health, to determine whether the data you require is collected and accessible? Yes ✔

Studies requiring PHA approval
Chapter 6 Part 4 of the Public Health Act 2005 (PHA) establishes the process for accessing health information held by Queensland Health for approved research projects. The PHA requires researchers to apply to the Director-General of QH or his/her delegate, for access to health information held by QH.

The PHA applies to all researchers (internal and external to Queensland Health) who are undertaking research using identifiable or potentially re-identifiable health information for which the researchers are unable to obtain participant consent to use their personal or identifying information for a clearly specified research study.

Details of the Public Health Act 2005 research provisions for access to confidential information may be found on the Queensland Health Research and Governance Unit site http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp.

8.2 Does this study require PHA approval? Yes ✔

8.3 PHA approval letter attached ✔
9. Research using information or resources of Clinical and Statewide Services (CaSS)

Authorization to Proceed from the Chief Executive Officer CaSS is required for any research project using information for which CaSS (including Pathology Queensland, Forensic and Scientific Services, Medication Services Queensland and other branches of CaSS) is the data custodian and for any research project involving CaSS staff or resources. This includes but is not limited to:

- Research projects using Pathology Queensland samples
- Clinical trials that require access to archived data and samples
- Clinical trials involving access to the resources of central pharmacy

The CaSS Coordination Planning and Research Unit (CPRU) is responsible for managing CaSS approval process and will assist researchers with this process.

For use of human tissue that is held by Queensland Health – Contact Research Office in Clinical and State-wide Services or visit: http://www.health.qld.gov.au/qhcss/research/info.asp

9.1 Is approval from Clinical and Statewide Services (CaSS) Research Committee required? Yes

9.2 CaSS approval letter attached ✓

9.3 Does this study require access to Pathology Queensland specimens? Yes ✓

9.4 Have you consulted directly with Pathology Queensland regarding access? Yes ✓

9.5 Does this study require Pathology Queensland tests or services? Yes ✓

9.6 Pathology Queensland quote and approval attached Yes ✓

10. Research involving access to coronial material

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

For further information please refer to Research Involving Material from Coroners’ Autopsies: Advice to ethics committees and researchers: http://www.health.qld.gov.au/qhcss/qhss/default.asp

10.1 Does this study require access to Coronial Material? No ✓

11. Research involving adults with impaired capacity to consent

Where a person is over the legal age of consent but is unable to give consent, written application to the Queensland Civil and Administrative Tribunal (QCAT) must be undertaken.

For further information please to the Queensland Civil and Administrative Tribunal: http://www.qcat.qld.gov.au/index.htm

Does this study involve adults with impaired capacity to consent No ✓
12. Research involving Aboriginal and Torres Strait Islander peoples including coincidental recruitment

Applicants should address the extent to which their application fulfils the following criteria in relation to research into the health of Indigenous Australians including documentation and other relevant written evidence where appropriate. The criteria are: Reciprocity and community engagement; Respect; Equality; Responsibility; Survival and protection; and Spirit and integrity.


12.1 Have the researchers had relevant community engagement with Aboriginal and Torres Strait Islander individuals, communities and/or organisations in conceptualisation, development and approval, data collection and management, analysis, report writing and dissemination of results for this study, relevant to this site? Yes ✔

12.2 Address the extent to which the application fulfils the criteria of Reciprocity and community engagement; Respect; Equality; Responsibility; Survival and protection; and Spirit and integrity in relation to research into the health of Indigenous Australians at this site.

Add details under each of the criteria:

**Reciprocity and community engagement:**
KKKK Disease is a significant health issue for Aboriginal and Torres St Islanders with rates of KKKK Disease in Aboriginal and Torres Strait Islanders up to 5x the rate of non Aboriginal and Torres St Islander peoples. Advances in the management of KKKK Disease in Indigenous people has the potential to benefit current and future generations. The researchers have consulted with the local Aboriginal and Torres Strait Islander Liaison Service who have provided feedback on the research design.

**Respect:**
Respect for the individual and their culture will be maintained throughout the study. All staff involved in this study are experienced and have training in dealing with different cultures, and respect the individuals rights, welfare, beliefs, perceptions, customs and cultural heritage. Potential participants will be offered the opportunity to have a support person and/or an Aboriginal and Torres Strait Islander Liaison Service representative present as requested.

**Equality:**
This is an international study, designed to accommodate many different cultures from around the world. The selection of participants does not discriminate on the grounds of race, sex or spiritual belief. However, because of the nature of the methodology and the importance of timing of the site visits, there may be geographical limitations and people living XXX distance from the site may be unlikely to be able to participate. This will be decided on a case to case basis.

**Responsibility:**
The Principal Investigator has overall responsibility for the conduct of the trial which will be conducted under the ICH GCP guidelines. The aim of this research is to benefit patients with XXX Disease. The research does not impact on cultural values as a result of the research.

**Survival and protection:**
Both the investigator and study coordinator have had previous positive research experience where Aboriginal and Torres Strait Islander peoples have been involved and understand and respect their cultures and beliefs. Any cultural distinctiveness can be accommodated under the terms of this protocol. Patients who agree to partake in this study will be allowing further research into XXXX disease particularly as it pertains to the Aboriginal and Torres Strait Islander peoples.

**Spirit and integrity:**
The researchers realise that Aboriginal and Torres Strait Islander communities are not homogeneous however they also recognise that there are core values and principles that remain common across the cultural spectrum. The researchers have, through the Aboriginal and Torres Strait Islander Liaison Service, approached and requested feedback from those Aboriginal and Torres Strait Islander communities who will be affected by the research.
13. Clinical trials

13.1 Please select the study phase (one only)

<table>
<thead>
<tr>
<th>Phase I clinical trial</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase II clinical trial</td>
<td></td>
</tr>
<tr>
<td>Phase III clinical trial</td>
<td>✓</td>
</tr>
<tr>
<td>Phase IV / post marketing surveillance</td>
<td></td>
</tr>
</tbody>
</table>

13.2 Research conducted under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes? Automatically populated from NEAF with ability to overwrite

Under the Clinical Trial Notification (CTN) scheme? Yes ✓

If yes, attach the relevant TGA Form (with relevant sections signed by the Principal Investigator and HREC Chair / delegate)

* A copy of the completed fully signed CTN / CTX Form must be submitted to the RGO.

13.3 Clinical trials registry

Section 19 of the Declaration of Helsinki (2008) states: “Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject”. In addition, the International Committee of Medical Journal Editors (ICMJE) has made an essential criterion for publication of a trial in one of their journals that the details of a trial should be publicly available in a clinical trials registry.

Is the clinical trial registered on a publicly accessible clinical trials registry database? No ✓

If no, please explain why the study is not registered on a publicly accessible clinical trials registry database

Registration to the ANZCTR will be completed prior to recruitment of first participant. These details will be submitted to the RGO when finalised.

14. Clinical Studies – indemnity and insurance

14.1 Is the Medicines Australia Standard Indemnity Form(s), signed by the sponsor attached? Yes ✓

14.2 Is there evidence of adequate insurance cover attached? Yes ✓
15. **Research Study Agreements**

All research studies involving entities external to QH require a study agreement. In addition, some studies involving multiple entities within QH require a study agreement.

15.1 Is there a written research study agreement, signed by all relevant parties attached?  
Yes ✓

If Yes, please indicate what type of study agreement:  
Industry Sponsored  
(a) Medicines Australia (MA) Standard Clinical Trial Agreement ✓

16. **Intellectual Property considerations**

16.1 Is there a possibility of new Intellectual Property to be developed from this project?  
Yes ✓  No □

16.2 Has a search of patent databases been undertaken?  
Yes ✓  No □


16.3 Does the contract state arrangements for the use of existing intellectual property and the parties' rights in relation to ownership?  
Yes ✓  No □  N/A □

16.4 Does the contract state arrangements for the use of all new intellectual property developed through the research project?  
Yes ✓  No □  N/A □

If the answer is 'yes' to 16.1 and 'no' to 16.2 and/or 16.3 and/or 16.4 then you should take the following steps:  
(i) Discuss the issue of incorporating intellectual property terms in the contract with your associates and any legal or business manager assisting with development of the contract; and  
(ii) Contact the Intellectual Property Unit within the Office of Health and Medical Research by emailing [ip_officer@health.qld.gov.au](mailto:ip_officer@health.qld.gov.au) to determine if the terms are suitable for Queensland Health.
17. **Biosafety, chemical and radiation safety – complete only if relevant to this site**

<table>
<thead>
<tr>
<th>17.1 Is Institutional Biosafety Committee (IBC) notification and/or licence application to the Office of the Gene Technology Regulator (OGTR) for approval of genetically modified organisms required?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>17.2 Will the project require NHMRC Gene and Related Therapies Research Advisory Panel (GTRAP) assessment? CTAC (Cellular Therapies Advisory Committee)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>17.3 Will the project require application for a licence to the NHMRC Licensing Committee to conduct embryo research?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ☐</td>
</tr>
</tbody>
</table>

Section 2.1.6 of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code on Exposure of Humans to Ionizing Radiation for Research states that a researcher 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.

<table>
<thead>
<tr>
<th>17.4 For projects where Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code compliance is required, is additional State-specific radiation safety approval and registration required?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ✓</td>
</tr>
</tbody>
</table>
18. Resource and Budget Information

Instructions for researchers:

Districts may incur costs in providing support for your research over and above those costs associated with standard care. Any costs over and above routine care which are to be met by the District are to be clearly identified and detailed. This includes both the ‘Actual’ costs and ‘In kind’ support. Confirmation of cost estimates, and agreement as to a funding source, is to be provided by the Director of Finance (or delegate) in the first instance before final authorisation by the District CEO or delegate.

18.1 Departments and services involved in research *

List the departments/locations involved in the research at this site.

<table>
<thead>
<tr>
<th>Department/location (e.g. Pathology, Allied Health)</th>
<th>Name of responsible person contacted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurology Department</td>
<td>Dr Darren Jenkins</td>
</tr>
<tr>
<td>Pathology Department</td>
<td>Dr Steven Vein</td>
</tr>
<tr>
<td>Diagnostic Imaging Department</td>
<td>Dr Erica Roento</td>
</tr>
</tbody>
</table>

* Note: A signed Declaration from the Head of Department or delegate must be attached with a completed SSA before Authorisation (see Declarations).

18.2 Study Budget - at this site

<table>
<thead>
<tr>
<th>Type of funding</th>
<th>Funder name</th>
<th>Amount for this site (either $/year or $/participant)</th>
<th>Sought or approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overseas Sources</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Business (commercially sponsored)</td>
<td>Acme Sponsor Company</td>
<td>$19000.00/participant completed.</td>
<td>Approved.</td>
</tr>
<tr>
<td>Private non-profit organisations (e.g collaborative groups)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donations/Bequests</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australian Government eg NHMRC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Joint Business/Government</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non Qld State/Local Government</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>University</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Qld Govt Department eg Treasury</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal institutional competitive research grants</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal department funds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Australian Sources</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (researcher self funded etc)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## 18.3 Site Finance Management

<table>
<thead>
<tr>
<th>Item(s)</th>
<th>Total monetary budget for the site $ / year</th>
<th>In kind costs (Y / N)</th>
<th>Cost covered by sponsor or funder (Y/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply of drugs and or other therapies.</td>
<td>Nil</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Radiology (MRI brain Scan x 10)</td>
<td>5032.00</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Pathology (4x venipuncture per patient x 10 pts)</td>
<td>2321.20</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Pharmacy (see pharmacy quote based on 6 dispensings / patient x 10 pts)</td>
<td>7200.00</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Diagnostics – other (3x ECG's per patient x 10 pts)</td>
<td>1062.00</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Principal Investigator (3 hrs / pt, Level MO4-1 - $91.00 / hr)</td>
<td>2730.00</td>
<td>Yes – from Q-Health</td>
<td>Yes</td>
</tr>
<tr>
<td>Co investigator(s) (6 hrs / pt, Level MO1-7 - $75.89 / hr)</td>
<td>4553.40</td>
<td>Yes – from Q-Health</td>
<td>Yes</td>
</tr>
<tr>
<td>Clinical study coordinator (16 hrs / FN, Grade 6-4 - $38.52)</td>
<td>16024.32 (per yr)</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Administrative support</td>
<td>Nil</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>Other Infrastructure e.g. computers, printing, office space, stationary etc.</td>
<td>($30/mth x 12 mths) 360.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use of equipment</td>
<td>Nil</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Patient Travel &amp; Accommodation Costs</td>
<td>As per Fee Schedule – calculated on as needs basis</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Staff Travel &amp; Accommodation Costs</td>
<td>All costs associated with study related matters covered by sponsor</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Archiving</td>
<td>As per Fee Schedule – costs covered by Sponsor</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>39282.92 per year</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Add additional lines as required.*

*Document only those items which are above the usual standard care and are particular to the research study eg extra documentation, extra tests etc.*

*If required by the local RGO, attach the relevant site specific departmental budgets.*

*The monetary costs need to be covered by a funds source(s) which may be existing source or new funds. The total costs (including monetary and in-kind) should be reported in surveys of research expenditure.*

If costs are not covered by the sponsor please explain how the costs will be covered or explain how institution will benefit from research.
18.4 Finance Authorisation

Cost allocations and sources have been agreed:

------------------------------------------------------------
Director of Finance / delegate name    Director of Finance / delegate signature    Date
------------------------------------------------------------
Principal Investigator name                   Principal Investigator signature                      Date

19. Funds Management Details

Identify the external organisation that will receive and manage the funding for this study if funds are not being managed by Queensland Health. Where the research is funded, Queensland Health has a responsibility to recover costs associated with research conducted at its facilities, please provide the following details for invoicing.

19.1 Invoice details

Organisation Name:

Contact person

Title
Surname:
First name:
Position:
Department:
Mailing address:
Suburb/Town:
State:
Post code:
Business phone number:
Mobile number:
Fax number:
Email address:
External administering organisation account details (account number):
ABN
For industry sponsored/CRO clinical trials provide the following details:

19.2 Sponsor details

Organisation Name: The Sponsor Company

Contact person

Title: Ms
Surname: Branson
First name: Victoria
Position: Accounts Manager
Department: Accounts Department (Research)
Mailing address: P.O. Box 4578
Suburb/Town: Melbourne
State: Victoria
Post code: 3100
Business phone number: 03 9987 4446
Mobile number: 0123 456 789
Fax number: 03 9987 4447
Email address: Branson@sponsor.com.au
ABN: 44 398 216 926

19.3 Contract Research Organisation (CRO) Details

Organisation Name: The Sponsor Company

Contact person (CRA)

Title: Ms
Surname: Gale
First name: Imelda
Position: Lead LRA
Department: Innovation and Research
Mailing address: P.O. Box 4578
Suburb/Town: Melbourne
State: Victoria
Post code: 3100
Business phone number: 03 9987 1234
Mobile number: 0419 876 532
Fax number: 03 9987 6547
Email address: Imelda.Gale@Thesponsorcompany.org.au
ABN: 44 398 216 946
If Queensland Health is the administering organisation provide details about the account number(s)/cost centre details into which funds are to be deposited. Where research is funded, Queensland Health has a responsibility to recover cost associated with research conducted at its facilities. Please provide details for invoicing.

Ensure the site principal investigator or the site Study Coordinator has a cost centre / internal order number set up for this project.

<table>
<thead>
<tr>
<th>QH Cost Centre # and / or internal Order / Tracking Number (Insert number in Table)</th>
</tr>
</thead>
</table>
20. Queensland Health Database of Research Activity

The Australia – Research Ethics Database (AU RED) is the online system used for the management and administration of all human research ethics & governance applications submitted to a Human Research Ethics Committee and/or Research Governance Office for studies conducted within Queensland Health.

The Database of Research Activity is a publicly accessible, searchable internet web site which takes an automatic download of research data from the AU-RED system and presents it in a format to allow researchers and other interested public stakeholders to search for and view summary level information about research being conducted in Queensland Health.

The searchable database covers all Queensland Health human research (not just clinical trials) and is designed to facilitate greater collaboration and communication between researchers, improve patients’ access to research information and raise awareness about the benefits of health and medical research.

20.1 Full Title

APRICOT: A Phase 3 Multicenter, Randomized, Placebo-Controlled, Double-Blind Twelve-Month Safety and Efficacy Study Evaluating XXXC in Patients with KKKK Disease who are receiving standard therapy.
Protocol No: KMB987456

20.2 Short title

The safety and efficacy of XXXC in patients with KKKK disease who are on standard therapy.

20.3 Type of study

Clinical trial of a drug

20.4 HREC reference Number

HREC/09/QPAH/654

20.5 Description of the Project in Plain Language

KKKK Disease is a disease which affects brain processes. The current medications available to treat this disease are limited. Thus, there is a need for new therapies with greater efficacy and/or effects on the rate of disease progression.

This study evaluates the safety and efficacy of XXXC in combination with standard therapy. This study will determine whether XXXC (study drug) combined with standard therapy improves the symptoms of KKKK disease. The study will evaluate two doses of oral KKKK (16 mg three times a day and 8 mg three times a day) administered for 12 months (52 weeks). The other countries participating in the study include New Zealand, Canada and the United States.

Approximately 1,050 patients will be centrally allocated into three groups of 350 patients each: XXXC 16 mg three times a day; XXXC 8 mg three times a day; and placebo. Standard therapy will be supplied as a study medication for all patients on the study.

The study is open to both males and females aged 50 year or older who have KKKK disease.

Participants will attend the clinic a total of 10 times and each visit should last about 3 hours. During these visits participants will be required to complete a number of questionnaires and tests to assess different brain functions.

A blood sample will be collected at the baseline visit to perform genetic blood tests. Pharmacogenetics is the study of how our genetic make-up affects how our bodies react to or handle medications. If it appears that there is a difference in patients’ responses to XXXC, the sponsor may study these differences using genetic material taken from these blood samples.

Safety and tolerability will be assessed by recording of adverse events and by monitoring of vital signs, physical examinations, safety laboratory evaluations, and 12-lead electrocardiograms (ECGs). An independent Data Monitoring Committee will monitor safety data in the trial on an ongoing basis.
20.6 NHMRC Category
Cardiology (incl. Cardiovascular Diseases)

20.7 Investigator at this site
Dr Johnathon Smithers

20.8 Contact person at this site
Ms Helen White
Helen.White@brains.com.au

20.9 Funding source

<table>
<thead>
<tr>
<th>Type of funding</th>
<th>Funder name</th>
<th>Amount for this site (either $/year or $/participant)</th>
<th>Sought or approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overseas Sources</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Business (commercially sponsored)</td>
<td>Acme Sponsor Company</td>
<td>$19000.00/participant completed.</td>
<td>Approved.</td>
</tr>
<tr>
<td>Private non-profit organisations (eg collaborative groups)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donations/Bequests</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australian Government eg NHMRC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Joint Business/Government</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non Qld State/Local Government</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>University</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Qld Govt Department eg Treasury</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal institutional competitive research grants</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal department funds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Australian Sources</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (researcher self funded etc)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please note: only the 'Funder Name' will be publicly visible. Details regarding: Type of funding; Amount; and Sought or Approved will not be released.

20.10 Anticipated start and finish dates
7.1 Start date * 12/12/2010
7.2 Finish date # 12/12/2014
7.3 Durations (months): 48 months
I, the local site Principal Investigator, have the authority to give consent for the above details to be uploaded onto the Queensland Health Database of Research Activity   Yes X   No □

I, the local site Principal Investigator, give consent for the above details for this site to be uploaded onto the Queensland Health Database of Research Activity   Yes □   No X

Explain why you do not give consent for the details of this study to be uploaded onto the Queensland Health Database of Research Activity

As there are IP implications regarding this research study I wish to delay the release of this information until the IP implications have been addressed.
21. Declarations
(a) Declaration by the Principal Investigator/Site Coordinator (s) and Associate Investigator(s) at this site

---

Project Title (in full): HREC/09/QPAH/654: APRICOT: A Phase 3 Multicenter, Randomized, Placebo-Controlled, Double-Blind Twelve-Month Safety and Efficacy Study Evaluating XXXC in Patients with KKKK Disease who are receiving standard therapy. Protocol No: KMB987456

HREC No. HREC/09/QPAH/654

Principal Investigator/Site Coordinator (s): Dr Johnathon Smithers

---

1. I declare the information in this form is truthful and accurate to the best of my knowledge and belief and I take full responsibility at this site.

2. I will only start this research project after obtaining authorisation from the site and approval from the responsible Human Research Ethics Committee (HREC);

3. I accept responsibility for the conduct of this research project according to the principles of the NHMRC National Statement on the Ethical Conduct in Human Research (2007) and the Australian Code for the Responsible Conduct of Research (2007) and Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)

4. I undertake to conduct this research project in accordance with the protocols and procedures as approved by the HREC and the ethical and research arrangements of the organisation(s) involved.

5. I undertake to conduct this research in accordance with relevant legislation and regulations.

6. I agree to comply with the requirements of adverse or unexpected event reporting as stipulated by the HREC and NHMRC

7. I will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements.

8. I will inform the HREC and the delegated department or Divisional Head if the research project ceases before the expected date. I will discontinue the research if the HREC withdraws ethical approval.

9. I will adhere to the conditions of authorisation stipulated by the authorising authority at the site where I am Principal Investigator. I will discontinue the research if the authorising authority withdraws authorisation at the site where I am Principal Investigator.

10. I understand and agree that study files and documents and research records and data may be subject to inspection by the HREC, the sponsor or an independent body for audit and monitoring purposes.

11. I understand that information relating to this research, and about me as a researcher, will be held by the Queensland Health HREC and on the Research Ethics Database (RED). This information will be used for reporting purposes and managed according to the principles established in the Privacy Act 1988 (Cth) and relevant laws in the States and Territories of Australia.

---

Print name of Principal Investigator: Dr Johnathon Smithers
Signature ........................................................................................................ Date ..........................

---

Print name of Site Coordinator: Ms Helen White
Signature ........................................................................................................ Date ..........................
Print name of Associate Investigator: Dr Miriam Thomas
Signature ………………………………………………………………………Date …………..
(b) Declaration by delegated Department Head/s at the site where the Principal Investigator/Site Coordinator will conduct the research for the purpose of resourcing the research project.

<table>
<thead>
<tr>
<th>Project Title (in full): HREC/09/QPAH/654: APRICOT: A Phase 3 Multicenter, Randomized, Placebo-Controlled, Double-Blind Twelve-Month Safety and Efficacy Study Evaluating XXXC in Patients with KKKK Disease who are receiving standard therapy. Protocol No: KMB987456</th>
</tr>
</thead>
<tbody>
<tr>
<td>HREC No. HREC/09/QPAH/654</td>
</tr>
<tr>
<td>Principal Investigator/Site Coordinator (s): Dr Johnathon Smithers</td>
</tr>
</tbody>
</table>

I certify that I have read the project details in this SSA for the research project application named above. I certify that I have discussed this research project and the resource implications for this Department, with the Principal Investigator/Site Coordinator.

I certify that there are suitable and adequate facilities and resources for the research project to be conducted at this site. This is for ‘Actual costs’ and ‘In kind’ contribution.

My signature indicates that I support this research project being carried out using such resources.

Name of Department: Neurology Department

Name of Head of Department / delegate: Dr Darren Jenkins

Signature: ………………………………………………………………………………………… Date: ……………………

Name of Department: …………………………………………………………………………………………

Name of Head of Department / delegate: …………………………………………………………………………………………

Signature: ………………………………………………………………………………………… Date: ……………………

*Where an investigator is also Head of Department, certification must be sought from the person to whom the Head of Department is responsible. Investigators must not approve their own research on behalf of their Department.
(c) Declaration by Head of Supporting Department / delegate at this site

This form is to be completed by the Head of any Department or delegate that is providing support or services to the research project, but which does not have any member(s) on the research team.

**Project Title (in full):** HREC/09/QPAH/654: APRICOT: A Phase 3 Multicenter, Randomized, Placebo-Controlled, Double-Blind Twelve-Month Safety and Efficacy Study Evaluating XXXC in Patients with KKKK Disease who are receiving standard therapy. Protocol No: KMB987456

**HREC No.** HREC/09/QPAH/654

**Principal Investigator/Site Coordinator(s):** Dr Johnathon Smithers

I have discussed this project with the Principal Investigator and have read the research project. I am (tick whichever applies)

- [ ] able to perform the investigations/services indicated, within the present resources of the Department;
- [x] able to perform the investigations/services indicated, if the following financial assistance is provided:

As per finance statement

- [ ] unable to undertake the investigations/services indicated, on the following grounds:

---

**Name** DR Steven Vein

**Department** Pathology … **Position** Head Of Department

**Signature** ………………………………………………………………………………………………………. **Date**………………

I have discussed this project with the Principal Investigator and have read the research project. I am (tick whichever applies)

- [ ] able to perform the investigations/services indicated, within the present resources of the Department;
- [x] able to perform the investigations/services indicated, if the following financial assistance is provided:

As per finance statement

- [ ] unable to undertake the investigations/services indicated, on the following grounds:
### 22. Checklist

**Checklist**

Please complete all the relevant components of the checklist with Yes: No: NA (Not Applicable). Include this checklist with the SSA Form for this site.

<table>
<thead>
<tr>
<th>Project Title (in full): HREC/09/QPAH/654: APRICOT: A Phase 3 Multicenter, Randomized, Placebo-Controlled, Double-Blind Twelve-Month Safety and Efficacy Study Evaluating XXXC in Patients with KKKK Disease who are receiving standard therapy. Protocol No: KMB987456</th>
<th>Person Completing Form</th>
<th>Office Use Only</th>
</tr>
</thead>
<tbody>
<tr>
<td>HREC No. HREC/09/QPAH/654</td>
<td>Yes: No: N/A</td>
<td>Yes: No: N/A</td>
</tr>
<tr>
<td>Principal Investigator/Site Coordinator (s): Dr Johnathon Smithers</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has a cover letter, with brief description of project; listing enclosed documents and application signed by local Principal Investigator been uploaded onto the ‘Documents Tab’ and is attached?</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Has a CV for each researcher (or on file) been uploaded onto the online forms under the ‘Documents Tab’?</td>
<td></td>
<td>On file</td>
<td></td>
</tr>
<tr>
<td>Has a site contact person for this research project been nominated?</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Has a copy of the HREC approval letter been uploaded onto the online forms under the ‘Documents Tab’ and is attached?</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Has a copy of the final approved NEAF been uploaded onto the online forms under the ‘Documents Tab’ and is attached?</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Has a copy of the protocol been uploaded onto the online forms under the ‘Documents Tab’ and is attached?</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Has a copy of the Investigator’s Brochure/drug information/device information been uploaded onto the online forms under the ‘Documents Tab’ and is attached?</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Are all Participant Information, Consent and Revocation Forms attached showing the name of the Institution as the letterhead, and contact details of the Principal Site Investigator? The version number and date, assigned HREC numbers and page numbers e.g. Page 1 of 10 should be in the footer?</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Have the local site Participant Information and Consent Form(s) been uploaded onto the online forms under the ‘Documents Tab’?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a copy of the advertisement been uploaded onto the online forms under the ‘Documents Tab’ and is attached?</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Has a copy of any questionnaires been uploaded onto the online forms under the ‘Documents Tab’ and is attached?</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Has a copy of any other document, which will be given to research participants been uploaded onto the online forms under the ‘Documents Tab’ and is attached? Eg: identification card, patient diary etc</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Has a copy of the Public Health Act (PHA) approval been uploaded onto the</td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>--------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a copy of the Clinical and Statewide Services (CaSS) approval been uploaded onto the online forms under the ‘Documents Tab’?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a copy of the Forensic &amp; Scientific Services approval been uploaded onto the online forms under the ‘Documents Tab’?</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a copy of the State Coroner’s approval been uploaded onto the online forms under the ‘Documents Tab’?</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a copy of the Queensland Civil Administration Tribunal (QCAT) approval been uploaded onto the online forms under the ‘Documents Tab’?</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If a clinical trial, are CTN/CTX forms, <strong>signed</strong> by the approving HREC and Principal Site Investigator attached?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the Medicines Australia Standard <em>Indemnity Form</em> or the Medicines Australia HREC Review Only <em>Indemnity Form signed</em> by the sponsor, been uploaded onto the online forms under the ‘Documents Tab’ and is attached?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the certificate of insurance cover attached adequate and current and has it been uploaded onto the online forms under the ‘Documents Tab’?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the relevant Medicines Australia or Queensland Health Standard Study Agreement, <strong>signed</strong> by the sponsor and Principal Investigator, been uploaded onto the online forms under the ‘Documents Tab’ and is attached?</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If not using a standard Medicines Australia or Queensland Health research agreement, is non standard research study agreement, which has been reviewed and approved by the relevant QH lawyer, <strong>signed</strong> and been uploaded onto the online forms under the ‘Documents Tab’ and is attached?</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has evidence of an application for NHMRC Cellular Therapies Advisory Committee (CTAC) been uploaded onto the online forms under the ‘Documents Tab’?</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has evidence of an application for a licence to the NHMRC Embryo Research Licensing Committee to conduct embryo research, been uploaded onto the online forms under the ‘Documents Tab’?</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has the <strong>Institutional Biosafety Committee</strong> (IBC) approval been uploaded onto the online forms under the ‘Documents Tab’?</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has evidence of Radiation Safety approval been uploaded onto the online forms under the ‘Documents Tab’?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you completed all the financial details?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the Resource and Budget Information Section, including the relevant signatures, completed?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has the Director of Finance or delegate authorisation of funds section been signed?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the Database of Research Activity (DORA) section completed?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the “Declaration by Principal Investigator” section signed?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the “Declaration by Site Coordinator” section signed?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>--------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the “Declaration by Associate Investigator/s” section signed?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the “Declaration by Head/s of Department” section signed?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the “Declaration by Head/s of Supporting Department” signed for each</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>supporting Department (if applicable)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are all pages (including attachments) numbered and dated in the footer?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

FORWARD YOUR COMPLETED SSA AND ALL RELEVANT SUPPORTING DOCUMENTATION TO THE SITE/DISTRICT RESEARCH GOVERNANCE OFFICE/R
23. Recommendation by RGO and sign off by District CEO / delegate

(e) Recommendation by the Research Governance Office/r at the site:

Project Title (in full): HREC/09/QPAH/654: APRICOT: A Phase 3 Multicenter, Randomized, Placebo-Controlled, Double-Blind Twelve-Month Safety and Efficacy Study Evaluating XXXC in Patients with KKKK Disease who are receiving standard therapy. Protocol No: KMB987456

HREC No. HREC/09/QPAH/654

Principal Investigator/Site Coordinator (s): Dr Johnathon Smithers

The Site-Specific Assessment (SSA) form for the above research project has been completed (with all attachments).

SSA authorisation is: □ Recommended

□ Not recommended

Requires Chief Executive/delegate consideration

If not recommended or requires Chief Executive/delegate consideration, give reasons.

Delegated Research Governance Office/r

Signature .............................................................. Date..........................
Authorisation by District CEO or delegate

Project Title (in full): HREC/09/QPAH/654: APRICOT: A Phase 3 Multicenter, Randomized, Placebo-Controlled, Double-Blind Twelve-Month Safety and Efficacy Study Evaluating XXXC in Patients with KKKK Disease who are receiving standard therapy. Protocol No: KMB987456

HREC No. HREC/09/QPAH/654

Principal Investigator/Site Coordinator(s): Dr Johnathon Smithers

This research is: authorised ☐ not authorised ☐

Specify, conditions applying to authorisation (if any) or reasons for not authorising.

My signature indicates that I authorise/ do not authorise this research project to commence at this site on the condition that all the scientific and ethical aspects of the Human Research Ethics Committee approved protocol are met.

Name of District CEO or delegate: ……………………………………………………………

Signature: …………………………………………………………………………………… Date: ………………

Name of the QH site for the research to be conducted ………………………………………

For those sites without access to the Australia – Research Ethics Database (AU RED): once authorisation is given, the District CEO / delegate should email a copy of the authorised SSA Form to the Research Ethics & Governance Office, Office of Health & Medical Research: REGU@health.qld.gov.au for uploading onto AU RED.

The Australia – Research Ethics Database (AU RED) is an online research ethics & governance management tool used by Queensland Health (QH) which is also used to capture all research conducted within QH facilities.
Appendix B: Site-Specific Assessment (SSA) Form – Non Clinical Trial Example

SSA is a component of research governance. It involves assessing the suitability of a site at which the research is being conducted and identifying whether the ‘actual’ and or ‘in kind’ resources required for the conduct and completion of the project can be met by the District. The SSA is the mechanism for financial accountability and transparency and is consistent with the Queensland Government Financial Accountability Act 2009. It is also a means by which Districts may quantify the contribution made by Queensland Health and manage and plan budgets.

Human Research Ethics Committee (HREC) approval of the research protocol is a pre-requisite for submission of an SSA at the research site. Final approval to conduct a study at a site requires:

- consideration and sign off of the financial commitment by the Director of Finance or delegate at the District/site; and
- the delegated District CEO or delegate to provide final sign off on the provision of resources at the site where the research is being conducted.

INSTRUCTIONS FOR THE PRINCIPAL INVESTIGATOR

- This form must be completed by the local site Principal Investigator or delegate where the research is being conducted. Not all sections of the form will be relevant.

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

- The SSA form must be forwarded to the District/site research governance personnel at the site of the research for consideration and checking prior to final Authorisation by the District CEO or delegate.

- All aspects of this SSA form are to be completed where relevant and the required associated documents attached.

- The checklist on the back of the SSA form will assist to ensure a full submission is completed before forwarding to the District/site research governance personnel at the site.

Limited information on this SSA has been populated from your final approved ethics application form. Please complete all sections that are relevant to the study and site at which the study is to be conducted.
1. **Project details**

**HREC Application Reference Number:** HREC/10/QPCH/775

**Name of HREC reviewing the research project:** The Prince Charles Hospital HREC (Automatically populated from NEAF)

**Give the name of the project site to which this SSA applies:** The Prince Charles Hospital, Qld

<table>
<thead>
<tr>
<th>Single site study</th>
<th>Multicentre study</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

**Title (in full):** “Provision of Support Services to the Novice Researcher – Does it impact Research Outcomes?” (Automatically populated from NEAF)

**Short title:** Research Support and Outcomes (Automatically populated from NEAF)

**Acronym:**

2. **Description of the Project in Plain Language**

Give a concise and simple description (not more than 400 words), in plain language, of the aims of this project, the proposal research design and the methods to be used to achieve those aims.

(Automatically populated from NEAF)

This is a prospective observational study examining the experiences of novice researchers undertaking their first research projects. Currently, the main support given to novice researchers is from within their work department, with a manager assigned to mentor the research. The problems with this process are that there is insufficient time to allow adequate supervision in the initiation and conduct of a research study.

In this project, novice researchers will be given additional support in the area of study design, protocol writing, completion of the NEAF and other application tools, statistical analysis as well as 15 hours/week of administrative support. Coaching in these areas of research competence will be conducted as one on one instruction, or in small groups when covering protocol writing and study design.

The assessment of the project will be via questionnaires which will be completed by researchers at significant points during the HREC approval process and throughout their research projects.

The aim of the project is to determine if extra coaching in significant areas and provision of administrative support will improve the quality of research completed, decrease researcher stress and increase research output.
3 Study type and NHMRC Group and Field of Research

3.1 Please select study type (one only) Mandatory field

<table>
<thead>
<tr>
<th>Study Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Research</td>
</tr>
<tr>
<td>Clinical trial of a drug</td>
</tr>
<tr>
<td>Clinical trial of a device</td>
</tr>
<tr>
<td>Other clinical trial</td>
</tr>
<tr>
<td>First time in human clinical trial /</td>
</tr>
<tr>
<td>First time in patient clinical trial</td>
</tr>
<tr>
<td>Health research / Social science</td>
</tr>
<tr>
<td>Other</td>
</tr>
</tbody>
</table>

3.2 Please select the NHMRC Group and sub Field of Research from the drop down boxes.

*The appropriate item is to be selected from the drop down boxes. These are mandatory fields and the SSA can not be progressed until these fields are completed. Mandatory fields*
4. Researcher(s)

Provide details of researchers at this site:

Provide details of researchers at this site:
(Use the 'mailbox' icon linked to the contacts list to enter the contact details more quickly)

4.1 Principal Investigator(s)

Title: Ms
First name: Annabella
Surname: Pitt
Mailing address: Research, Ethics and Governance Office, Country District Hospital
Suburb/Town: Gumdale
State: Queensland
Post code: 4154
Country, if not Australia:
Organisation Name: Country District Hospital
Position in organisation: Research Educator
Business hours phone number: 07 1234 5678
Fax number: 07 8765 4321
Email address: Annabella_Pitt@blah.com.au

Medical staff only:

Have you been credentialled at a Queensland Health District? [ ] Yes [ ] No [ ] N/A X
What is the expiry date? (___/___/____)

Does the credentialing scope of clinical practice cover all the relevant aspects of the investigator’s participation in this study? [ ] Yes [ ] No

How will this deficit in credentialing be addressed?

For some research studies the local site PI may be the Coordinating PI. For all studies there must be an onsite contact person.

4.2 Associate Investigator(s)

(Use the 'mailbox' icon linked to the contacts list to enter the contact details more quickly)

Add as many Associate Investigators as required for this site

Title: Ms
First name: Matilda
Surname: Moneypenny
Mailing address: Research, Ethics and Governance Office, Country District Hospital
Suburb/Town: Gumdale
State: Queensland
Post code: 4154
Country, if not Australia:
Organisation Name: Country District Hospital
Position in organisation: Research Psychologist
Business hours phone number: 07 1234 5678
Medical staff only:
Have you been credentialed at a Queensland Health District? Yes ☐ No ☐ N/A X
What is the expiry date? (___/___/____)
Does the credentialing scope of clinical practice cover all the relevant aspects of the investigator’s participation in this study Yes ☐ No ☐

How will this deficit in credentialing be addressed?
4.3 * Contact person at this site for this research project
(Use the ‘mailbox’ icon linked to the contacts list to enter the contact details more quickly)

Title: Ms
First name: Annabella
Surname: Pitt
Mailing address: Research, Ethics and Governance Office, Country District Hospital
Suburb/Town: Gumdale
State: Queensland
Post code: 4154
Country, if not Australia:
Country, if not Australia:
Organisation Name: Country District Hospital
Position in organisation: Research Educator
Business hours phone number: 07 1234 5678
Fax number: 07 8765 4321
Email address: Annabella_Pitt@blah.com.au

* The PI will be responsible for ensuring there is a Contact Person at the site who will liaise with the District/site research governance personnel. The contact person may be the PI or a person nominated by the PI however they must be located at the site.
5. Training
Will any of the researchers at this site require extra training to enable their participation in this project?  Yes ☐  No ☐  N/A ☐

If Yes, list the researchers, describe the training that is required and who will provide this training – at this site.

<table>
<thead>
<tr>
<th>Researcher</th>
<th>Training required</th>
<th>Who will provide training?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annabella Pitt</td>
<td>Interpretation of Questionnaires</td>
<td>Matilda Moneypenny – Project Psychologist.</td>
</tr>
</tbody>
</table>

6. Recruitment
6.1 Recruitment process
What process will be used to identify potential participants for the study at this site?

(Automatically populated from NEAF)
All researchers who are either unknown to the HREC office and have submitted a HREC application, or who are known to be novice researchers will be contacted by the HREC Administration Support Officer to ascertain their interest in participating in this project. In addition, notification of this project will be placed in the institutions Research Newsletter, and novice researchers will be invited to nominate to participate in this project.

6.2 Recruitment at the site NEAF 6.15
Describe how initial contact will be made with potential participants at this site.

(Automatically populated from NEAF)
The HREC Administration Support Officer will either speak directly with novice researchers when they contact the HREC office or will telephone them to notify them of this research project and ascertain their level of interest in participating.

Those researchers who indicate a willingness to participate will be emailed the Participant Information Sheet and Consent form, and their contact details will be forwarded to the Principal Investigator for follow up.

6.3 How many Participants at this site
What is the proposed number of participants to be recruited?
20

6.4 Participant details NEAF 6.1
What categories of people will be recruited at this site? (e.g. children and young people, people with an intellectual or mental impairment, people highly dependent on medical care, people in dependent or unequal relationships, Aboriginal & Torres Strait Islander people, persons in custody, etc).
7. Provide the anticipated start and finish dates for the research project at this site.

(Automatically populated from NEAF)
7.1 Start date * 01 Feb 2012
7.2 Finish date # 30 Nov 2012
7.3 Duration: 10 months

* Start date refers to the anticipated first point of recruitment i.e. the date when the advertising or screening for participants begins.
# Finish date refers to when no further contact with participants/data source is foreseen including the data analysis and reporting period.

8. Queensland Health policy on access to confidential information held by the Department.

All studies
8.1 Have you consulted with the data custodian/s regarding access to Confidential Information held by Queensland Health, to determine whether the data you require is collected and accessible? Yes ✓ No □

Studies requiring PHA approval
Chapter 6 Part 4 of the Public Health Act 2005 (PHA) establishes the process for accessing health information held by Queensland Health for approved research projects. The PHA requires researchers to apply to the Director-General of QH or his/her delegate, for access to health information held by QH.

The PHA applies to all researchers (internal and external to Queensland Health) who are undertaking research using identifiable or potentially re-identifiable health information for which the researchers are unable to obtain participant consent to use their personal or identifying information for a clearly specified research study.

Details of the Public Health Act 2005 research provisions for access to confidential information may be found on the Queensland Health Research and Governance Unit site http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp.

8.2 Does this study require PHA approval? Yes □ No ✓

9. Research using information or resources of Clinical and Statewide Services (CaSS)

Authorisation to Proceed from the Chief Executive Officer CaSS is required for any research project using information for which CaSS (including Pathology Queensland, Forensic and Scientific Services, Medication Services Queensland and other branches of CaSS) is the data custodian and for any research project involving CaSS staff or resources. This includes but is not limited to:

- Research projects using Pathology Queensland samples
- Clinical trials that require access to archived data and samples
- Clinical trials involving access to the resources of central pharmacy

The CaSS Coordination Planning and Research Unit (CPRU) is responsible for managing CaSS approval process and will assist researchers with this process.

For use of human tissue that is held by Queensland Health – Contact Research Office in Clinical and State-wide Services or visit: http://www.health.qld.gov.au/qhcss/research/info.asp

9.1 Is approval from Clinical and Statewide Services (CaSS) Research Committee required? Yes □ No ✓

9.3 Does this study require access to Pathology Queensland specimens? Yes □ No ✓
10. Research involving access to coronial material

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

For further information please refer to Research Involving Material from Coroners’ Autopsies: Advice to ethics committees and researchers: http://www.health.qld.gov.au/qhcss/qhss/default.asp

10.1 Does this study require access to Coronal Material?  Yes ☐ No ✓

11. Research involving adults with impaired capacity to consent

Where a person is over the legal age of consent but is unable to give consent, written application to the Queensland Civil and Administrative Tribunal (QCAT) must be undertaken.

For further information please to the Queensland Civil and Administrative Tribunal:

Does this study involve adults with impaired capacity to consent Yes ☐ No ✓

12. Research involving Aboriginal and Torres Strait Islander peoples including coincidental recruitment

Applicants should address the extent to which their application fulfils the following criteria in relation to research into the health of Indigenous Australians including documentation and other relevant written evidence where appropriate. The criteria are: Reciprocity and community engagement; Respect; Equality; Responsibility; Survival and protection; and Spirit and integrity.


12.1 Have the researchers had relevant community engagement with Aboriginal and Torres Strait Islander individuals, communities and/or organisations in conceptualisation, development and approval, data collection and management, analysis, report writing and dissemination of results for this study, relevant to this site? Yes ☐ No ✓

Explain why community consultation has not been sought?

This study is a single site prospective observational study examining the experiences of novice researchers undertaking their first research projects. Ethnicity is not relevant to the aims of this research study. There are only a minimal number of novice researchers who identify themselves as of ATSI background.

12.2 Address the extent to which the application fulfils the criteria of Reciprocity and community engagement; Respect; Equality; Responsibility; Survival and protection; and Spirit and integrity in relation to research into the health of Indigenous Australians at this site.

N/A
14. Clinical Studies – indemnity and insurance

14.1 Is the Medicines Australia Standard Indemnity Form(s), signed by the sponsor attached?  
N/A ✓

Explain why Medicines Australia Standard Indemnity Form(s) is not attached

Single site study involving QH staff only

14.2 Is there evidence of adequate insurance cover attached?  
N/A ✓

Explain why insurance cover documentation is not attached.

Single site study involving QH staff only
### 15. Research Study Agreements

*All research studies involving entities external to QH require a study agreement. In addition, some studies involving multiple entities within QH require a study agreement.*

<table>
<thead>
<tr>
<th>15.1 Is there a written research study agreement, signed by all relevant parties attached?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ☐ No ☐ N/A ✓ - If no or N/A please give an explanation</td>
</tr>
</tbody>
</table>

**Single site study involving QH staff only**

If Yes, please indicate what type of study agreement:

- **Industry Sponsored**
  - (a) Medicines Australia (MA) Standard Clinical Trial Agreement ☐
  - (b) Endorsed Standard CRO CTA ☐

- **Collaborative Organisation**
  - (c) Endorsed Standard Collaborative CTA ☐

- **Industry Sponsored Device trial**
  - (d) Endorsed Standard Device CTA ☐

- **Post marketing surveillance / Phase IV study**
  - (e) Endorsed Standard Post marketing surveillance / Phase IV CA ☐

- **Investigator initiated clinical trial**
  - (f) Endorsed Standard Investigator initiated CTA ☐

- **Other**
  - (g) Non standard study agreement (e.g. University etc; not a - f above) ☐

Name of organisation entering into contract with Qld Health (Uni, Collaborative group name etc)

```
……………………………………………………………………
```

Has the non standard study agreement been reviewed and approved by an approved Qld Health legal team? Yes ☐ No ☐

Please explain why the non standard study agreement has not been reviewed and approved by an approved Qld Health legal team?

```

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*If no, the non standard agreement will need review by the District or Area Health Services Lawyer relevant to your District. If your district does not have a District Lawyer, please refer to the Research Management Policy and Framework*

*If a sponsor wishes to use their own contract, or have amendments made to a standard, QH approved CTA, a written undertaking should be obtained from the sponsor to pay for any legal fees incurred by Queensland Health for review of the non-standard contract.*

**NOTE:** For Qld Health – the delegated authority to sign ALL Clinical Trial Agreements is the responsibility of the District CEO or delegate. For other signing delegations refer to the QH Contract Signing Delegation
16. Intellectual Property considerations

16.1 Is there a possibility of new Intellectual Property to be developed from this project?

Yes ☐ No ✓

17. Biosafety, chemical and radiation safety – complete only if relevant to this site

It may be necessary for research organisations to complete notification, registration or licence requirements for research involving biosafety, regulatory issues and/or radiation. If so, evidence of this is required.

17.1 Is Institutional Biosafety Committee (IBC) notification and/or licence application to the Office of the Gene Technology Regulator (OGTR) for approval of genetically modified organisms required? Yes ☐ No ✓

17.2 Will the project require NHMRC Gene and Related Therapies Research Advisory Panel (GTRAP) assessment? CTAC (Cellular Therapies Advisory Committee) Yes ☐ No ✓

17.3 Will the project require application for a licence to the NHMRC Licensing Committee to conduct embryo research? Yes ☐ No ✓

Section 2.1.6 of the Australian Radiation Protection and Nuclear Safety Agency (ARP ANSA) Code on Exposure of Humans to Ionising Radiation for Research states that a researcher 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.

17.4 For projects where Australian Radiation Protection and Nuclear Safety Agency (ARP ANSA) Code compliance is required, is additional State-specific radiation safety approval and registration required? Yes ☐ No ✓
18. Resource and Budget Information

Instructions for researchers:

Districts may incur costs in providing support for your research over and above those cost associated with standard care. Any costs over and above routine care which are to be met by the District are to be clearly identified and detailed. This includes both the 'Actual' costs and 'In kind' support. Confirmation of cost estimates, and agreement as to a funding source, is to be provided by the Director of Finance (or delegate) in the first instance before final authorisation by the District CEO or delegate.

18.1 Departments and services involved in research *

List the departments/locations involved in the research at this site.

<table>
<thead>
<tr>
<th>Department/location (e.g. Pathology, Allied Health)</th>
<th>Name of responsible person contacted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research, Ethics and Governance Office</td>
<td>Mr Ima Wiseman</td>
</tr>
<tr>
<td>Mental Health Services</td>
<td>Dr Serene</td>
</tr>
</tbody>
</table>

* Note: A signed Declaration from the Head of Department or delegate must be attached with a completed SSA before Authorisation (see Declarations).

18.2 Study Budget - at this site

<table>
<thead>
<tr>
<th>Type of funding</th>
<th>Funder name</th>
<th>Amount for this site (either $/year or $/participant)</th>
<th>Sought or approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overseas Sources</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Business (commercially sponsored)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private non-profit organisations (eg collaborative groups)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donations/Bequests</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australian Government eg NHMRC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Joint Business/Government</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non Qld State/Local Government</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>University</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Qld Govt Department eg Treasury</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal institutional competitive research grants</td>
<td>Country District Hospital Foundation Grant</td>
<td>$50,000.00</td>
<td>Approved.</td>
</tr>
<tr>
<td>Internal department funds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Australian Sources</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (researcher self funded etc)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## 18.3 Site Finance Management

<table>
<thead>
<tr>
<th>Item/s</th>
<th>Total monetary budget for the site $ / year</th>
<th>In kind costs (Y / N)</th>
<th>Cost covered by sponsor or funder (Y/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply of drugs and or other therapies.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiology</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pathology</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnostics - other</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Principal Investigator</td>
<td>In kind support</td>
<td>No – approved under normal department work time</td>
<td></td>
</tr>
<tr>
<td>Co investigator(s)</td>
<td>In kind support</td>
<td>No – approved under normal department work time</td>
<td></td>
</tr>
<tr>
<td>Clinical study coordinator</td>
<td>$40,000.00</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Administrative support</td>
<td>$5000.00</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Other Infrastructure e.g. computers, printing, office space, stationary etc.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use of equipment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Travel &amp; Accommodation Costs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff Travel &amp; Accommodation Costs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Archiving</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>$5000.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>$50,000.00</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Add additional lines as required.
Document only those items which are above the usual standard care and are particular to the research study eg extra documentation, extra tests etc.
If required by the local RG0, attach the relevant site specific departmental budgets.
The monetary costs need to be covered by a funds source(s) which may be existing source or new funds. The total costs (including monetary and in-kind) should be reported in surveys of research expenditure.

If costs are not covered by the sponsor please explain how the costs will be covered or explain how institution will benefit from research

Costs will not go beyond the grant amount. The monies allocated are for the purposes of providing administrative support to the 20 novice researchers and for the purpose of administering and analysing the questionnaires.
**18.4 Finance Authorisation**

Cost allocations and sources have been agreed:

<table>
<thead>
<tr>
<th>Director of Finance / delegate name</th>
<th>Director of Finance / delegate signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Principal Investigator name</th>
<th>Principal Investigator signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**19. Funds Management Details**

*Identify the external organisation that will receive and manage the funding for this study if funds are not being managed by Queensland Health. Where the research is funded, Queensland Health has a responsibility to recover costs associated with research conducted at its facilities, please provide the following details for invoicing.*

**19.1 Invoice details**

**Organisation Name:**

**Contact person**

Title  
Surname:  
First name:  
Position:  
Department:  
Mailing address:  
Suburb/Town:  
State:  
Post code:  
Business phone number:  
Mobile number:  
Fax number:  
Email address:  
External administering organisation account details (account number):  
ABN
For industry sponsored/CRO clinical trials provide the following details:

19.2 Sponsor Details

Organisation Name:

Contact person
Title
Surname:
First name:
Position:
Department:
Mailing address:
Suburb/Town:
State:
Post code:
Business phone number:
Mobile number:
Fax number:
Email address:
ABN

19.3 Contract Research Organisation (CRO) Details

Organisation Name:

Contact person (CRA)
Title
Surname:
First name:
Position:
Department:
Mailing address:
Suburb/Town:
State:
Post code:
Business phone number:
Mobile number:
Fax number:
Email address:
ABN
19.4 If Queensland Health is the administering organisation provide details about the *account number(s)/cost centre details* into which funds are to be deposited. Where research is funded, Queensland Health has a responsibility to recover cost associated with research conducted at its facilities. Please provide details for invoicing.

Ensure the site principal investigator or the site Study Coordinator has a cost centre / internal order number set up for this project.

**QH Cost Centre # and / or internal Order / Tracking Number (Insert number in Table)**

| CO 124879 |   |   |   |
20. Queensland Health Database of Research Activity

The Database of Research Activity is a publicly accessible, searchable internet web site which takes an automatic download of research data from the AU-RED system and presents it in a format to allow researchers and other interested public stakeholders to search for and view summary level information about research being conducted in Queensland Health.

20.1 Full Title

“Provision of Support Services to the Novice Researcher – Does it impact Research Outcomes?”

20.2 Short title

Research Support and Outcomes

20.3 Type of study

Health research / Social science

20.4 HREC reference Number

HREC/10/QPCH/775

20.5 Description of the Project in Plain Language

This is a prospective observational study examining the experiences of novice researchers undertaking their first research projects. Currently, the main support given to novice researchers is from within their work department, with a manager assigned to mentor the research. The problems with this process are that there is insufficient time to allow adequate supervision in the initiation and conduct of a research study.

In this project, novice researchers will be given additional support in the area of study design, protocol writing, completion of the NEAF and other application tools, statistical analysis as well as 15 hours/week of administrative support. Coaching in these areas of research competence will be conducted as one on one instruction, or in small groups when covering protocol writing and study design.

The assessment of the project will be via questionnaires which will be completed by researchers at significant points during the HREC approval process and throughout their research projects.

The aim of the project is to determine if extra coaching in significant areas and provision of administrative support will improve the quality of research completed, decrease researcher stress and increase research output.

20.6 NHMRC Category

Effective health care

20.7 Investigator at this site

Ms Annabella Pitt

20.8 Contact person at this site

Ms Annabella Pitt

Annabella_Pitt@blah.com.au
## 20.9 Funding source

<table>
<thead>
<tr>
<th>Type of funding</th>
<th>Funder name</th>
<th>Amount for this site (either $/year or $/participant)</th>
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<tr>
<td>Non Qld State/Local Government</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>University</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Qld Govt Department eg Treasury</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal institutional competitive research grants</td>
<td>Country District Hospital Foundation Grant</td>
<td>$50,000.00</td>
<td>Approved.</td>
</tr>
<tr>
<td>Internal department funds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Australian Sources</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (researcher self funded etc)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Please note: only the 'Funder Name' will be publicly visible. Details regarding: Type of funding; Amount; and Sought or Approved will not be released.*

## 20.10 Anticipated start and finish dates

Start date 01 Feb 2012  
Finish date 30 Nov 2012  
Duration: 10 months

I, the local site Principal Investigator, have the authority to give consent for the above details to be uploaded onto the Queensland Health Database of Research Activity  
Yes X  
No ☐

I, the local site Principal Investigator, give consent for the above details for this site to be uploaded onto the Queensland Health Database of Research Activity  
Yes X  
No ☐
21. Declarations

(a) Declaration by the Principal Investigator/Site Coordinator (s) and Associate Investigator(s) at this site

Project Title (in full): “Provision of Support Services to the Novice Researcher – Does it impact Research Outcomes?”
Principal Investigator/Site Coordinator (s): Ms Annabella Pitt
HREC No: HREC/10/QPCH/775

7. I declare the information in this form is truthful and accurate to the best of my knowledge and belief and I take full responsibility at this site.
8. I will only start this research project after obtaining authorisation from the site and approval from the responsible Human Research Ethics Committee (HREC);
9. I accept responsibility for the conduct of this research project according to the principles of the NHMRC National Statement on the Ethical Conduct in Human Research (2007) and the Australian Code for the Responsible Conduct of Research (2007) and Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)
10. I undertake to conduct this research project in accordance with the protocols and procedures as approved by the HREC and the ethical and research arrangements of the organisation(s) involved.
11. I undertake to conduct this research in accordance with relevant legislation and regulations.
12. I agree to comply with the requirements of adverse or unexpected event reporting as stipulated by the HREC and NHMRC.
13. I will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements.
14. I will inform the HREC and the delegated department or Divisional Head if the research project ceases before the expected date. I will discontinue the research if the HREC withdraws ethical approval.
15. I will adhere to the conditions of authorisation stipulated by the authorising authority at the site where I am Principal Investigator. I will discontinue the research if the authorising authority withdraws authorisation at the site where I am Principal Investigator.
16. I understand and agree that study files and documents and research records and data may be subject to inspection by the HREC, the sponsor or an independent body for audit and monitoring purposes.
17. I understand that information relating to this research, and about me as a researcher, will be held by the Queensland Health HREC and on the Research Ethics Database (RED). This information will be used for reporting purposes and managed according to the principles established in the Privacy Act 1988 (Cth) and relevant laws in the States and Territories of Australia.

Print name of Principal Investigator: Ms Annabella Pitt
Signature ……………………………………………………………………………Date  ………………..

Print name of Site Coordinator… Ms Annabella Pitt
(b) Declaration by delegated Department Head/s at the site where the Principal Investigator/Site Coordinator will conduct the research for the purpose of resourcing the research project.

<table>
<thead>
<tr>
<th>Project Title (in full):</th>
<th>“Provision of Support Services to the Novice Researcher – Does it impact Research Outcomes?”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator/Site Coordinator (s):</td>
<td>Ms Annabella Pitt</td>
</tr>
<tr>
<td>HREC No:</td>
<td>HREC/10/QPCH/775</td>
</tr>
</tbody>
</table>

I certify that I have read the project details in this SSA for the research project application named above. I certify that I have discussed this research project and the resource implications for this Department, with the Principal Investigator/Site Coordinator. I certify that there are suitable and adequate facilities and resources for the research project to be conducted at this site. This is for ‘Actual costs’ and ‘In kind’ contribution. My signature indicates that I support this research project being carried out using such resources.

<table>
<thead>
<tr>
<th>Name of Department:</th>
<th>Research, Ethics and Governance Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Head of Department / delegate…</td>
<td>Mr Ima Wiseman</td>
</tr>
<tr>
<td>Signature</td>
<td>……………………………………………………………………………………………………..Date …………………..</td>
</tr>
</tbody>
</table>

*Where an investigator is also Head of Department, certification must be sought from the person to whom the Head of Department is responsible. Investigators must not approve their own research on behalf of their Department.*
(c) Declaration by Head of Supporting Department / delegate at this site

This form is to be completed by the Head of any Department or delegate that is providing support or services to the research project, but which does not have any member(s) on the research team.

| Project Title (in full): “Provision of Support Services to the Novice Researcher – Does it Impact Research Outcomes?” |
| Principal Investigator/Site Coordinator (s): Ms Annabella Pitt |
| HREC No: HREC/10/QPCH/775 |

I have discussed this project with the Principal Investigator and have read the research project. I am (tick whichever applies)

- [X] able to perform the investigations/services indicated, within the present resources of the Department;
- [ ] able to perform the investigations/services indicated, if the following financial assistance is provided:

- [ ] unable to undertake the investigations/services indicated, on the following grounds:

<table>
<thead>
<tr>
<th>Name</th>
<th>Dr Serene</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department</td>
<td>…Mental Health Unit…….Position .Head of Department…</td>
</tr>
<tr>
<td>Signature</td>
<td>………………………………………………………………………………………………… Date…………………</td>
</tr>
</tbody>
</table>
22. Checklist

**Checklist**

Please complete all the relevant components of the checklist with Yes: No: NA (Not Applicable). Include this checklist with the SSA Form for this site.

<table>
<thead>
<tr>
<th>Project Title (in full): &quot;Provision of Support Services to the Novice Researcher – Does it impact Research Outcomes?&quot;</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator/Site Coordinator (s): Ms Annabella Pitt</td>
<td></td>
</tr>
<tr>
<td>HREC No: HREC/10/QPCH/775</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has a cover letter, with brief description of project; listing enclosed documents and application signed by local Principal Investigator been uploaded onto the 'Documents Tab' and is attached?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a CV for each researcher (or on file) been uploaded onto the online forms under the 'Documents Tab'?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a site contact person for this research project been nominated?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a copy of the HREC approval letter been uploaded onto the online forms under the 'Documents Tab' and is attached?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a copy of the final approved NEAF been uploaded onto the online forms under the 'Documents Tab' and is attached?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a copy of the protocol been uploaded onto the online forms under the 'Documents Tab' and is attached?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a copy of the Investigator’s Brochure/drug information/device information been uploaded onto the online forms under the 'Documents Tab' and is attached?</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are all Participant Information, Consent and Revocation Forms attached showing the name of the Institution as the letterhead, and contact details of the Principal Site Investigator? The version number and date, assigned HREC numbers and page numbers e.g. Page 1 of 10 should be in the footer?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have the local site Participant Information and Consent Form(s) been uploaded onto the online forms under the 'Documents Tab'?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a copy of the advertisement been uploaded onto the online forms under the 'Documents Tab' and is attached?</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a copy of any questionnaires been uploaded onto the online forms under the 'Documents Tab' and is attached?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a copy of any other document, which will be given to research participants been uploaded onto the online forms under the 'Documents Tab' and is attached? Eg: identification card, patient diary etc</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a copy of the Public Health Act (PHA) approval been uploaded onto the</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Site Specific Assessment Form Guidance –NON Clinical Trial Example
Prepared by the Office of Health and Medical Research | 17 June 2010: Version 3
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has a copy of the Clinical and Statewide Services (CaSS) approval been uploaded onto the 'Documents Tab'?</td>
<td>N/A</td>
</tr>
<tr>
<td>Has a copy of the Forensic &amp; Scientific Services approval been uploaded onto the 'Documents Tab'?</td>
<td>N/A</td>
</tr>
<tr>
<td>Has a copy of the State Coroner’s approval been uploaded onto the online forms under the 'Documents Tab'?</td>
<td>N/A</td>
</tr>
<tr>
<td>Has a copy of the Queensland Civil Administration Tribunal (QCAT) approval been uploaded onto the online forms under the 'Documents Tab'?</td>
<td>N/A</td>
</tr>
<tr>
<td>If a clinical trial, are CTN/CTX forms, signed by the approving HREC and Principal Site Investigator attached?</td>
<td>N/A</td>
</tr>
<tr>
<td>Is the Medicines Australia Standard Indemnity Form or the Medicines Australia HREC Review Only Indemnity Form signed by the sponsor, been uploaded onto the online forms under the ‘Documents Tab’ and is attached?</td>
<td>N/A</td>
</tr>
<tr>
<td>Is the certificate of insurance cover attached adequate and current and has it been uploaded onto the online forms under the ‘Documents Tab'?</td>
<td>N/A</td>
</tr>
<tr>
<td>Is the relevant Medicines Australia or Queensland Health Standard Study Agreement, signed by the sponsor and Principal Investigator, been uploaded onto the online forms under the ‘Documents Tab’ and is attached?</td>
<td>N/A</td>
</tr>
<tr>
<td>If not using a standard Medicines Australia or Queensland Health research agreement, is non standard research study agreement, which has been reviewed and approved by the relevant QH lawyer, signed and been uploaded onto the online forms under the ‘Documents Tab’ and is attached?</td>
<td>N/A</td>
</tr>
<tr>
<td>Has evidence of an application for NHMRC Cellular Therapies Advisory Committee (CTAC) been uploaded onto the online forms under the ‘Documents Tab’?</td>
<td>N/A</td>
</tr>
<tr>
<td>Has evidence of an application for a licence to the NHMRC Embryo Research Licensing Committee to conduct embryo research, been uploaded onto the online forms under the ‘Documents Tab’?</td>
<td>N/A</td>
</tr>
<tr>
<td>Has the <a href="http://www.health.qld.gov.au/ohmr">Institutional Biosafety Committee</a> (IBC) approval been uploaded onto the online forms under the ‘Documents Tab’?</td>
<td>N/A</td>
</tr>
<tr>
<td>Has evidence of Radiation Safety approval been uploaded onto the online forms under the ‘Documents Tab’?</td>
<td>N/A</td>
</tr>
<tr>
<td>Have you completed all the financial details?</td>
<td>Yes</td>
</tr>
<tr>
<td>Is the Resource and Budget Information Section, including the relevant signatures, completed?</td>
<td>Yes</td>
</tr>
<tr>
<td>Has the Director of Finance or delegate authorisation of funds section been signed?</td>
<td>Yes</td>
</tr>
<tr>
<td>Is the Database of Research Activity (DORA) section completed?</td>
<td>Yes</td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Is the “Declaration by Principal Investigator” section signed?</td>
<td>Yes</td>
</tr>
<tr>
<td>Is the “Declaration by Site Coordinator” section signed?</td>
<td>Yes</td>
</tr>
<tr>
<td>Is the “Declaration by Associate Investigator/s” section signed?</td>
<td>Yes</td>
</tr>
<tr>
<td>Is the “Declaration by Head/s of Department” section signed?</td>
<td>Yes</td>
</tr>
<tr>
<td>Is the “Declaration by Head/s of Supporting Department” signed for each supporting Department (if applicable)?</td>
<td>Yes</td>
</tr>
<tr>
<td>Are all pages (including attachments) numbered and dated in the footer?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

FORWARD YOUR COMPLETED SSA AND ALL RELEVANT SUPPORTING DOCUMENTATION TO THE SITE/DISTRICT RESEARCH GOVERNANCE OFFICE/R
23. Recommendation by RGO and sign off by District CEO / delegate

(e) Recommendation by the Research Governance Office/r at the site:

**Project Title (in full):** “Provision of Support Services to the Novice Researcher – Does it impact Research Outcomes?”

**Principal Investigator/Site Coordinator (s):** Ms Annabella Pitt

**HREC No:** HREC/10/QPCH/775

The Site-Specific Assessment (SSA) form for the above research project has been completed (with all attachments).

SSA authorisation is:

- Recommended
- Not recommended
- Requires Chief Executive/delegate consideration

If not recommended or requires Chief Executive/delegate consideration, give reasons.

Delegated Research Governance Office/r

Signature ................................................................. Date...........................
(f) Authorisation by District CEO or delegate

Project Title (in full): “Provision of Support Services to the Novice Researcher – Does it impact Research Outcomes?”

Principal Investigator/Site Coordinator (s): Ms Annabella Pitt

HREC No: HREC/10/QPCH/775

This research is: □ authorised □ not authorised

Specify, conditions applying to authorisation (if any) or reasons for not authorising.

My signature indicates that I authorise/ do not authorise this research project to commence at this site on the condition that all the scientific and ethical aspects of the Human Research Ethics Committee approved protocol are met.

Name of District CEO or delegate: .................................................................

Signature: ................................................................. Date: .....................

Name of the QH site for the research to be conducted ....................................

For those sites without access to the Australia – Research Ethics Database (AU RED):

once authorisation is given, the District CEO / delegate should email a copy of the authorised SSA Form to the Research Ethics & Governance Office, Office of Health & Medical Research: REGU@health.qld.gov.au for uploading onto AU RED.

The Australia – Research Ethics Database (AU RED) is an online research ethics & governance management tool used by Queensland Health (QH) which is also used to capture all research conducted within QH facilities.

http://creativecommons.org/licenses/by/2.5/au/

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