



**Queensland**  
Government  
Queensland Health

**Site Specific Assessment Form  
(SSA form)  
Guidance Standard**

**Nov 2009**

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# Guidance in using the Standard Site Specific Assessment Form (SSA Form)

## 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 Management Standards* (1997). 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* 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 Principal Investigator or in the case of multi-centre research, by the 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. The final Declaration/s on the SSA Form may only be signed off once HREC approval has been given. 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:

<https://ethicsform.org/Au/Forms/ManageSsaFormDocuments.aspx?Id=15135&SifFormId=23635&EditType=100>.

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.

If the site does not have an RGO contact the relevant HREC reviewing the study for instructions.

The following information is intended to provide guidance to researchers in completing the standard SSA. At the end of the online NEAF application the researcher will automatically be taken to a new form which will ask '*Please select whether you want to raise a SSA or PHA form*'. Researchers should click on the SSA Form box and complete the form.

Parts of the SSA form will be automatically populated with information from the QH National Ethics Application Form (NEAF). However, researchers will be 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**

### **Section 1: Project Details**

#### **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, (see QH Researcher User Guide for instructions):  
[http://www.health.qld.gov.au/ohmr/documents/researcher\\_userguide.pdf](http://www.health.qld.gov.au/ohmr/documents/researcher_userguide.pdf).

#### **Specific Guidance:**

The information pertaining to the "Title", of the study will be automatically populated from NEAF.

For multicentre 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.

### **Section 2: Description of Project**

#### **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.

#### **Specific Guidance:**

This information will be automatically populated from the NEAF.

### **Section 3: Study type, NHMRC & ABS area of research**

#### **Purpose:**

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

#### **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

*Broad Area of Research:*

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 category and subcategory:*

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

*ABS Field and subfield:*

The ABS Fields of Research (FoR) classification enables research and development to be classified in terms of its discipline and describes the nature of the research being done. These are required for the biannual ABS report.

*ABS Objectives and sub objective:*

The ABS Socio - Economic Objectives code classification allows research and development activities to be classified in terms of the main area of expected national benefit. It describes the end purpose of the research being performed. The purpose categories take account of processes, products, health, education and other social and environmental aspects of particular interest. These are required for the biannual ABS report

Information regarding the ABS categories can be obtained from contacting the ABS on: 1300 135 070, [client.services@abs.gov.au](mailto:client.services@abs.gov.au) or the ABS website: <http://www.abs.gov.au/ausstats/abs@.nsf/0/3C6A9D3AD3B68011CA25697E0018FC5E?opendocument>

#### **Section 4: Research Personnel**

**Purpose:**

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

**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.

## **Section 5: Training:**

### **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.

### **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.

## **Section 6: Recruitment of Participants**

### **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.

### **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.

## **Section 7: Anticipated start and finish dates for the research project**

### **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.

### **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.

## **Section 8: Access to confidential information held by QH**

### **Purpose:**

The provision of this information enables the RGO to ensure that access to confidential health information held by QH meets the research requirements under s281 of the *Public Health Act 2005*.

[http://www.health.qld.gov.au/ohmr/documents/pha\\_legislation\\_2005.pdf](http://www.health.qld.gov.au/ohmr/documents/pha_legislation_2005.pdf)

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://qheps.health.qld.gov.au/qhcss/research/cass\\_approval.htm](http://qheps.health.qld.gov.au/qhcss/research/cass_approval.htm)

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

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 3636 9865 or website: [http://qheps.health.qld.gov.au/qhcss/research/research\\_home.htm](http://qheps.health.qld.gov.au/qhcss/research/research_home.htm).

## **Section 9: Clinical Trials**

### **Purpose:**

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

### **Specific Guidance:**

9.1 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.

9.2 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 9.2 will automatically populate from the NEAF.

9.3 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.

9.4 The provision of this information (insurance and indemnity documents) enables the RGO to assess whether the required insurance and indemnity provisions are adequate. 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%20Only%20version%20230507B.doc>

## **Section 10: Clinical Study Agreements**

### **Purpose:**

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

### **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> should be used.

#### ***Collaborative Sponsored CTA:***

In the case of a collaborative sponsored clinical trial, the Medicines Australia Standard Clinical Trial Agreement for Collaborative or Cooperative Research Group (CRG) Studies should be used: <http://www.medicinesaustralia.com.au/pages/images/Standard-CRG-CTRA.doc>

#### ***Industry Sponsored Device Trial CTA:***

QH, in collaboration with MA, is developing a standard Industry Sponsored Device Trial CTA (due for completion early 2010). Please refer to the MA website:

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

#### ***Post marketing surveillance study CSA:***

QH is developing a standard post marketing surveillance study CA (due for completion early 2010). Please refer to the REGU website:

[http://www.health.qld.gov.au/ohmr/html/regu/regu\\_home.asp](http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp)

#### ***Investigator Initiated Clinical Trial CTA:***

QH, in collaboration with MA, is developing a standard Investigator Initiated Clinical Trial CTA (due for completion early 2010). Please refer to the MA website:

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

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.

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*)".

## **Section 11: Intellectual Property Considerations**

### **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.

### **Specific Guidance:**

The QH Intellectual Property Policy referred to in this section is located at:

[http://www.health.qld.gov.au/hspl/intell\\_property/qh\\_ip\\_policy.pdf](http://www.health.qld.gov.au/hspl/intell_property/qh_ip_policy.pdf)

and

[http://www.health.qld.gov.au/hspl/intell\\_property/ip2\\_ownership.pdf](http://www.health.qld.gov.au/hspl/intell_property/ip2_ownership.pdf)

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](mailto:ip_officer@health.qld.gov.au) to determine if the terms are suitable for Queensland

## **Section 12: Biosafety, Chemical and Radiation safety**

### **Purpose:**

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

### **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 radiation safety licensed persons at

<http://www.health.qld.gov.au/radiationhealth/default.asp>

## **Section 13: Resource and Budget Information**

### ***Section 13.1: Departments & services involved in the research***

#### **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.

#### **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 13.2: Study Budget at the Site***

#### **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.

#### **Specific Guidance:**

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

### ***Section 13.3: Site Finance Management***

#### **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.

**Specific Guidance:**

Information should be as accurate as possible, identifying the breakdown of the study budget.

**Section 13.4: Finance Authorisation****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*.

**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.

**Section 14: Funds Management****Purpose:**

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

**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.

**Section 15: Declarations****Section 15a: Declarations from investigators and site coordinator****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 15b: Declarations from Head of Department or delegate where the research project will be conducted****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 15c: Declarations from Head of Department or delegate providing support and/or services to the research project***

**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.

**Appendix A: SSA FORM EXAMPLE CLINICAL TRIAL**

**Appendix B: SSA FORM EXAMPLE NON CLINICAL TRIAL**

## QUEENSLAND HEALTH Site-Specific Assessment (SSA) Form Appendix A 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 Management Standard (1997)*. 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 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 Principal Investigator or in the case of multi-centre research, by the 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.
- **Negotiations with the relevant Heads of Departments or delegate and Director of Finance or delegate should commence and run parallel to the HREC approval cycle.** The final Declaration/s 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/09/ QPAH /654

**Name or ID # 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

**Title (in full):** NEAF 1.1 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 (Automatically populated from NEAF)

**Short title:** NEAF 1.1 "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 NEAF 1.2 and 5.3**

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 achieve those aims).

**(Automatically populated from NEAF)**  
K K K K 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 K K K K disease. The study will evaluate two doses of oral K K K K (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 K K K K 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, Broad Area of Research, NHMRC and Australian Bureau of Statistics (ABS) categories**

**3.1 Please select study type (one only)**

Clinical Research	<input type="checkbox"/>
Clinical trial of a drug / device	<input checked="" type="checkbox"/>
First time in human clinical trial / First time in patient clinical trial	<input type="checkbox"/>
Health research / Social science	<input type="checkbox"/>
Other	<input type="checkbox"/>

3.2 Please select the broad area of research (one only)

Basic Science	<input type="checkbox"/>
Clinical Medicine & Science	<input checked="" type="checkbox"/>
Preventative Medicine	<input type="checkbox"/>
Health Services Research	<input type="checkbox"/>
Public Health	<input type="checkbox"/>

3.3 Please select the NHMRC category and sub category 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.*

3.4 Please select the ABS field and subfield 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.*

3.5 Please select the ABS objective and sub objective 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.*

4. **Researcher(s)**

Provide details of researchers at this site:

**4.1 Principal Investigator(s) NEAF 2.1**  
**Append an attachment if there are more than one Principal Investigator. Include the details as listed below.**  
*(Use the 'mailbox' icon linked to the contacts list to enter the contact details more quickly)*

Title: Dr  
 First name: Johnathon  
 Surname: Smithers  
 Mailing address: C/- Neurology Department, The General Hospital  
 Suburb/Town: Brandenville  
 State: Queensland  
 Post code: 4111  
 Country, if not Australia:  
 Organisation Name: The General Hospital  
 Position in organisation: Neurologist  
 Business hours phone number: + 61 7 1234 5678  
 Fax number: + 61 7 8765 4321  
 Email address: Johnathon.smithers@brains.com.au  
 Have you been credentialed at a Queensland Health District? Yes ✓  
 What is the scope of Privilege? Qualified to practice as a consultant neurologist  
 What is the expiry date? 30.06.2010 (renewed annually)

**4.2 Associate Investigator(s) NEAF 2.2**  
**Append an attachment if there are more than one Associate Researchers. Include the details as listed below.**  
 (Use the 'mailbox' icon linked to the contacts list to enter the contact details more quickly)

Title: Dr  
 First name: Miriam  
 Surname: Thomas  
 Mailing address: C/- Neurology Department, The General Hospital  
 Suburb/Town: Brandenville  
 State: Queensland  
 Post code: 4111  
 Country, if not Australia:  
 Organisation Name: The General Hospital  
 Position in organisation: Neurologist  
 Business hours phone number: + 61 7 1234 5678  
 Fax number: + 61 7 8765 4321  
 Email address: Miriam.Thomas@brains.com.au  
 Have you been credentialed at a Queensland Health District? Yes ✓  
 What is the scope of Privilege? Qualified to practice as a consultant neurologist  
 What is the expiry date? 30.06.2010 (renewed annually)

**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  
 Country, if not Australia:  
 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.

**5. Training NEAF 2.7**

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.

Researcher	Training required	Who will provide training?
Dr Johnathon Smithers	Information about the Investigational product, study protocol, procedures and assessments	Sponsor company at the Investigator Meeting
Dr Miriam Thomas	Information about the Investigational product, study protocol, procedures and assessments	Sponsor company at the Investigator Meeting
Ms Helen White	Information about the Investigational product, study protocol, procedures and assessments	Sponsor company at the Investigator Meeting

## 6. Recruitment

### 6.1 Recruitment process *NEAF 6.13 and 6.14*

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

Automatically populated from NEAF

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 *NEAF 6.15*

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

Automatically populated from NEAF

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 participants

### 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).

Automatically populated from NEAF

## 7. Provide the anticipated start and finish dates for the research project at this site. *NEAF 4.4*

Automatically populated from NEAF

7.1 Start date \* (01/Mar/2010)

7.2 Finish date # (01/Mar 2012)

7.3 Duration (24 months):

\* Start date refers to the 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.**

**8.1** Does the project require access to Confidential Information held by Queensland Health?  
Yes ✓

**8.2** If so, have you consulted with the data custodian to determine whether the data you require is collected and accessible?  
Yes ✓

**Details of the *Public Health Act 2005* research provisions for access to confidential information may be found on the Queensland Health Research and Ethics Advisory Unit site [http://www.health.qld.gov.au/ohmr/html/regu/aces\\_conf\\_hth\\_info.asp](http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp). Application process and forms are available on this site.**

**For use of human tissue that is held by Queensland Health – Contact Research Office in Clinical and Statewide Services or visit [http://qhops.health.qld.gov.au/qhcss/research/research\\_home.htm](http://qhops.health.qld.gov.au/qhcss/research/research_home.htm)**

**9. Clinical trials**

**9.1 Please select the study phase (one only)**

Phase I clinical trial	<input type="checkbox"/>
Phase II clinical trial	<input type="checkbox"/>
Phase III clinical trial	<input checked="" type="checkbox"/>
Phase IV / post marketing surveillance	<input type="checkbox"/>

**9.2 Research conducted under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes? NEAF 9.2**

(Automatically populated from NEAF)

Under the Clinical Trial Notification (CTN) scheme? Yes ✓ No

Under the Clinical Trial Exemption (CTX) scheme? Yes  No

If yes, attach the relevant TGA Form (with relevant sections completed by the Principal Investigator and HREC).

### 9.3 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? Yes  No

If yes, please provide the name of the clinical trials registry and the study reference number.

Clinical trials registry name: ANZCTR

Study registry reference number... Q09/1000

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

### 9.4. Clinical Trials – indemnity and insurance

If the study is a sponsored clinical trial the following sections must be completed, if relevant for this site

**9.4.1** Is the Medicines Australia Standard Indemnity Form(s), signed by the sponsor attached?

Yes  No  N/A  - If no or N/A please give an explanation.

**9.4.2** Is there evidence of adequate insurance cover attached?

Yes  No  N/A  - If no or N/A please give an explanation.

## 10. Clinical Study Agreements

Is there a written research contract, signed by all relevant parties attached?

Yes  No  N/A  - If no or N/A please give an explanation

If Yes, please indicate what type of contract:

Industry Sponsored

(a) Medicines Australia (MA) Standard Clinical Trial Agreement

Contract Research Organisation

(b) MA Standard CRO CTA

Collaborative Organisation

(c) MA Standard Collaborative CTA

Industry Sponsored Device trial

(d) MA Standard Device CTA

Post marketing surveillance study

(e) QH Standard Post marketing surveillance CA

Investigator initiated clinical trial

(f) MA 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

If yes, please complete

Name of legal team	Reviewed by (lawyer name)	Date reviewed	Reviewed for: Institution / District name

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 [http://www.health.qld.gov.au/ohmr/documents/res\\_man\\_pol\\_fram08.pdf](http://www.health.qld.gov.au/ohmr/documents/res_man_pol_fram08.pdf)

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.

Fee for Service Research by QH Clinical and Statewide Services (CaSS)

**NOTE: For Qld Health – the delegated authority to sign ALL contracts is the responsibility of the District CEO or delegate.**

## 11. Intellectual Property considerations

<p><b>11.1</b> Is there a possibility of new Intellectual Property to be developed from this project?</p> <p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p> <p><b>11.2</b> Has a search of patent databases been undertaken?</p> <p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p> <p>Step by step assistance on searching patent databases is available in IP Fact sheet 1 titled "Information for Medical Researchers" at: <a href="http://www.health.qld.gov.au/ohmr/html/rcpu/intel_prop.asp">http://www.health.qld.gov.au/ohmr/html/rcpu/intel_prop.asp</a></p> <p><b>11.3</b> Does the contract state arrangements for the use of existing intellectual property and the parties' rights in relation to ownership? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/></p> <p><b>11.4</b> Does the contract state arrangements for the use of all new intellectual property developed through the research project? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/></p> <p>If the answer is 'yes' to 11.1 and 'no' to 11.2 and/or 11.3 and/or 11.4 then you should take the following steps:</p> <p>(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</p> <p>(ii) Contact the Intellectual Property Unit within the Office of Health and Medical Research by emailing <a href="mailto:ip_officer@health.qld.gov.au">ip_officer@health.qld.gov.au</a> to determine if the terms are suitable for Queensland Health.</p>
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## 12. Biosafety, chemical and radiation safety – complete only if relevant to this site

<p>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. If "yes" is ticked below, appropriate documentation of approval must be attached or forwarded to the site's Research Governance Officer when available.</p> <p><b>12.1.</b> 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 <input type="checkbox"/> Attached <input type="checkbox"/> No <input checked="" type="checkbox"/></p> <p><b>12.2.</b> Is committee approval of chemical safety required (drugs/pharmacy committee)? Yes <input checked="" type="checkbox"/> Attached <input checked="" type="checkbox"/> No <input type="checkbox"/></p> <p><b>12.3.</b> Will the project require NHMRC Gene and Related Therapies Research Advisory Panel (GTRAP) assessment? CTAC (Cellular Therapies Advisory Committee) Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p> <p><b>12.4.</b> Will the project require application for a licence to the NHMRC Licensing Committee to conduct embryo research? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p> <p><b>12.5.</b> 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? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/></p>
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### 13. 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 equivalent) in the first instance before final authorisation by the District CEO or delegate.*

#### **13.1 Departments and services involved in research \***

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

<b>Department/location (e.g. Pathology, Allied Health)</b>	<b>Name of responsible person</b>
Neurology Department	Dr Darren Jenkins
Pathology Department	Dr Steven Vein
Diagnostic Imaging Department	Dr Erica Roento

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

#### **13.2 Study Budget - at this site**

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

### 13.3 Site Finance Management

Item/s	Monetary cost for the site \$	Per patient costs \$	Funds source (Cost centre)	Cost covered by sponsor or funder (Y/N)
Supply of drugs and or other therapies.	Nil		Journal transfer from Neurology	NA
Radiology (MRI Brain Scan x 10)	5500.00	550.00	Research Cost Centre, A/C No:12345678	Yes
Pathology (4 x venepunctures/patient)	480.00	48.00		Yes
Pharmacy (See pharmacy quote based on 6 dispensings/patient)	7200.00	720.00		Yes
Diagnostics – other (3 x ECG's/patient)	2400.00	240.00		Yes
Principal Investigator 3 hrs/pt (Level MO4-1: \$87.08/hr)	2612.40	261.24		No. *In kind support from QH
Co investigator(s) 6 hrs/pt (Level MO1-7: \$72.62/hr)	4357.20	435.72	No. *In kind support from QH	
Clinical study coordinator (Grade 6-4 nurse, 0.25FTE)	\$703.76/fortnight/52 \$36595.52		A/C No:12345678	Yes
Administrative support	Nil			NA
Other Infrastructure e.g. computers, printing, office space, stationary etc.	\$30/mth x 24 mths \$720.00		A/C No:12345678	Yes
Use of equipment	Nil			NA
Patient Travel & Accommodation Costs	As per Matrix. Calculated on "as needed" basis.		A/C No:12345678	Yes
Staff Travel & Accommodation Costs	All costs associated with attendance at study related meetings will be covered by the Sponsor.			Yes
Archiving	As per Matrix. Costs will be covered by Sponsor.			Yes
Other				
<b>Total</b>	<b>59865.12 over 24 months</b>		A/C No:12345678	

- **"In kind support"** No fees charged for these services. Neurology Department will meet these costs.
  - **Add additional lines as required**
- 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 associated with Investigator and co-investigator time have been provided, in-kind, by the Neurology Department, Brandenville Hospital. No fees will be levied against the Research Cost Centre for this service

### 13.4 Finance Authorisation

Costs allocations and sources have been agreed:

Ivan Centimo.	.....	.....
Director of Finance / delegate name	Director of Finance / delegate signature	Date
Dr Johnathon Smithers	.....	.....
Principal Investigator name	Principal Investigator signature	Date

## 14. 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.

### 14.1 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):

For industry sponsored/CRO clinical trials provide the following details:

### 14.2 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:

### 14.3 Contract Research Organisation (CRO) Details

Organisation: **The Sponsor Company**  
Name:  
**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](mailto:Imelda.Gale@Thesponsorcompany.org.au)

**14.4** 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 Trial Coordinator has a cost centre set up for this project.

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

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clinical trial example

**15. Declarations**

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

(Automatically populated)

**HREC Application Reference number: HREC/09/QPAH/654**

**Project Title (in full): NEAF 1.1 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**

**Principal Investigator (s) or Contact person (at this site): NEAF 2.1 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 **ICH GCP**
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.**

(Automatically populated)

**HREC Application Reference number: HREC/09/QPAH/654**

**Project Title (in full): NEAF 1.1 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**

**Principal Investigator (s) or Contact person (at this site): NEAF 2.1 Dr Johnathon Smithers**

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.....**Medical Imaging Department

**Name of Head of Department / delegate** Dr Erica Roento

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

**Name of Department...**Pathology Department

**Name of Head of Department / delegate** Dr Steven Vein .

**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.

**(Automatically populated)**  
**HREC Application Reference number: HREC/09/QPAH/654**

**Project Title (in full): NEAF 1.1 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**

**Principal Investigator (s) or Contact person (at this site): NEAF 2.1 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;
- 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:

**Name:** Dr Erica Roento.....

**Department** Medical Imaging Department ..... **Position** ..Director, Medical Imaging

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

**Name:** Dr Steven Vein .....

**Department** Pathology Department ..... **Position** .. Director, Brandenville Hospital Pathology Laboratory

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

## 16. 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.

<b>HREC Application Reference number: HREC/09/QPAH/654</b>		
<b>Project Title (in full): NEAF 1.1 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</b>		
<b>Principal Investigator (s) or Contact person (at this site): NEAF 2.1 Dr Johnathon Smithers</b>		

	Person Completing Form Yes:No:NA	Office Use Only Yes:No:N/A
Has a CV been attached for each researcher (or on file)?	Yes	
Have you attached proof of Professional Medical Registration (or on file)?	Yes	
Has a contact person for this research project been nominated?	Yes	
Have you completed all financial details?	Yes	

Has a copy of the HREC approval letter been provided?	Yes	
Has a copy of the final approved NEAF form been provided?	Yes	
Has a copy of the protocol been provided?	Yes	
Has a copy of the Investigator's Brochure/drug information/device information been provided?		No
Are all Participant Information and Consent Form(s) attached and show the name of the Institution and contact details of the Principal Site Investigator? The version number, standard organisation name and date should be in the footer.	Yes	
Has a copy of advertising been provided?		No
Has a copy of any questionnaires been provided?		No
Has a copy of any other document, which will be given to research participants been provided? Eg: identification card, patient diary		No

If a clinical trial, are CTN/CTX forms, <b>signed</b> by the approving HREC and Principal Site Investigator attached?	Yes	
Is the Medicines Australia Standard <i>Indemnity Form</i> , <b>signed</b> by the sponsor, attached?	Yes	
Is evidence of adequate insurance cover attached?	Yes	
Is the <u>relevant</u> Medicines Australia or Queensland Health Standard Study <i>Agreement(s)</i> , <b>signed</b> by the sponsor, attached?	Yes	
If not using the Medicines Australia or Queensland Health contract is the relevant documentation <b>signed</b> and attached?		
Has evidence of Biosafety approval been provided?		No
Has committee approval of chemical safety been provided (pharmacy/drug)?	Yes	

Has evidence of an application for NHMRC Cellular Therapies Advisory Committee (CTAC) been provided?		No
Has evidence of an application for a licence to the NHMRC Embryo Research Licensing Committee to conduct embryo research, been provided?		No
Has evidence of Radiation Safety approval been provided?	Yes	
Have you included any other site-specific policy documents required by the Institution(s) at which you intend to conduct your research? <i>Example Approval under the Public Health Act 2005 to access confidential health information for the purposes of research</i>	Yes	

Has the Resource and Budget Information Section completed?	Yes	
Has Director of Finance or delegate authorised funds (if required)?	Yes	
Is a "Declaration by Principal Investigator" signed and attached?	Yes	
Is a "Declaration by Head/s of Department" signed and attached?	Yes	
Is a "Declaration by Head of Supporting Department" signed and attached for each supporting Department (if applicable)?	Yes	
Are all pages (including attachments) numbered and dated in the footer?	Yes	

**FORWARD YOUR COMPLETED SSA AND A COPY OF YOUR HREC APPROVAL TO THE SITE/DISTRICT RESEARCH GOVERNANCE OFFICE/R**

clinical trial example

**17. Recommendation by RGO and sign off by District CEO**

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

<p><b>HREC Application Reference number: HREC/09/QPAH/654</b></p> <p><b>Project Title (in full): NEAF 1.1 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</b></p> <p><b>Principal Investigator (s) or Contact person (at this site): NEAF 2.1 Dr Johnathon Smithers</b></p>
--

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

SSA authorisation is:

Recommended	<input type="checkbox"/>
Not recommended	<input type="checkbox"/>
Requires Chief Executive/delegate consideration	<input type="checkbox"/>

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

<p>ical trial example</p>
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Delegated Research Governance Office/r .....	
Signature .....	Date.....

**(f) Authorisation by District CEO or delegate**

**HREC Application Reference number: HREC/09/QPAH/654**

**Project Title (in full): NEAF 1.1 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**

**Principal Investigator (s) or Contact person (at this site): NEAF 2.1 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** .....

**QUEENSLAND HEALTH**  
**Site-Specific Assessment (SSA) Form**  
**Appendix B General Research Study 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 Management Standard (1997)*. 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 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 Principal Investigator or in the case of multi-centre research, by the 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.
- **Negotiations with the relevant Heads of Departments or delegate and Director of Finance or delegate should commence and run parallel to the HREC approval cycle.** The final Declaration/s 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/09/QPCH/775

**Name or ID # 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

**Title (in full):** NEAF 1.1 "Provision of Support Services to the Novice Researcher – Does it impact Research Outcomes?" (Automatically populated from NEAF)

**Short title:** NEAF 1.1 Research Support and Outcomes (Automatically populated from NEAF)

**Acronym:**

**2. Description of the Project in Plain Language NEAF 1.2 and 5.3**

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 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.

**4 Study type, Broad Area of Research, NHMRC and Australian Bureau of Statistics (ABS) categories**

**4.1 Please select study type (one only)**

Clinical Research	<input type="checkbox"/>
Clinical trial of a drug / device	<input type="checkbox"/>
First time in human clinical trial / First time in patient clinical trial	<input type="checkbox"/>
Health research / Social science	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

**4.2 Please select the broad area of research (one only)**

Basic Science	<input type="checkbox"/>
Clinical Medicine & Science	<input type="checkbox"/>
Preventative Medicine	<input type="checkbox"/>
Health Services Research	<input checked="" type="checkbox"/>
Public Health	<input type="checkbox"/>

**3.3 Please select the NHMRC category and sub category 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.*

**3.4 Please select the ABS field and subfield 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.*

**3.5 Please select the ABS objective and sub objective 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.*

#### 4. Researcher(s)

**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) NEAF 2.1

**Append an attachment if there is more than one Principal Investigator. Include the details as listed below.**

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

Have you been credentialed at a Queensland Health District? N/A ✓

What is the scope of Privilege?

What is the expiry date? ( / / )

##### 4.2 Associate Investigator(s) NEAF 2.2

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

**Append an attachment if there is more than one Associate Researcher. Include the details as listed below.**

Title: Ms

First name: Matilda

Surname: Money Penny

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

Fax number: 07 8765 4321

Email address: Matilda\_Moneypenny@blah.com.au

Have you been credentialed at a Queensland Health District? N/A ✓

What is the scope of Privilege?

What is the expiry date? ( / / )

**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.

**5. Training NEAF 2.7**

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.

Researcher	Training required	Who will provide training?
Annabella Pitt	Interpretation of Questionnaires	Matilda Moneypenny – Project Psychologist.

**7. Recruitment**

**6.1 Recruitment process NEAF 6.13 and 6.14**

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).

(Automatically populated from NEAF)
-------------------------------------

### 7. Provide the anticipated start and finish dates for the research project at this site. *NEAF 4.4*

(Automatically populated from NEAF) 7.1 Start date * 01 Feb 2010: 7.2 Finish date # 30 Nov 2010: 7.3 Duration: 10 months
---

\* Start date refers to the 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.

<p>8.1 Does the project require access to Confidential Information held by Queensland Health? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p> <p>8.2 If so, have you consulted with the data custodian to determine whether the data you require is collected and accessible? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p><b>Details of the <i>Public Health Act 2005</i> research provisions for access to confidential information may be found on the Queensland Health Research and Ethics Advisory Unit site <a href="http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp">http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp</a>. Application process and forms are available on this site.</b></p> <p><b>For use of human tissue that is held by Queensland Health – Contact Research Office in Clinical and Statewide Services or visit <a href="http://qhps.health.qld.gov.au/qhcss/research/research_home.htm">http://qhps.health.qld.gov.au/qhcss/research/research_home.htm</a></b></p>
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## 9. Clinical trials

### 9.1 Please select the study phase (one only)

Phase I clinical trial	<input type="checkbox"/>
Phase II clinical trial	<input type="checkbox"/>
Phase III clinical trial	<input type="checkbox"/>
Phase IV / post marketing surveillance	<input type="checkbox"/>

### 9.2 Research conducted under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes? NEAF 9.2

(Automatically populated from NEAF)

Under the Clinical Trial Notification (CTN) scheme? Yes  No

Under the Clinical Trial Exemption (CTX) scheme? Yes  No

If yes, attach the relevant TGA Form (with relevant sections completed by the Principal Investigator and HREC).

### 9.3 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? Yes  No

If yes, please provide the name of the clinical trials registry and the study reference number.

Clinical trials registry name: .....

Study registry reference number: .....

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

### 9.4. Clinical Trials – indemnity and insurance

If the study is a sponsored clinical trial the following sections must be completed, if relevant for this site

**9.4.1** Is the Medicines Australia Standard Indemnity Form(s), signed by the sponsor attached?

Yes  No  N/A  - If no or N/A please give an explanation.

**9.4.2** Is there evidence of adequate insurance cover attached?

Yes  No  N/A  - If no or N/A please give an explanation.

**10. Clinical Study Agreements**

Is there a written research contract, signed by all relevant parties attached?

Yes  No  N/A  If no or N/A please give an explanation

This is an in house research study conducted entirely within the institution.

If Yes, please indicate what type of contract:

Industry Sponsored

(a) Medicines Australia (MA) Standard Clinical Trial Agreement

Contract Research Organisation

(b) MA Standard CRO CTA

Collaborative Organisation

(c) MA Standard Collaborative CTA

Industry Sponsored Device trial

(d) MA Standard Device CTA

Post marketing surveillance study

(e) QH Standard Post marketing surveillance CA

Investigator initiated clinical trial

(f) MA 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

If yes, please complete

Name of legal team	Reviewed by (lawyer name)	Date reviewed	Reviewed for: Institution / District name

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 [http://www.health.qld.gov.au/ohmr/documents/res\\_man\\_pol\\_fram08.pdf](http://www.health.qld.gov.au/ohmr/documents/res_man_pol_fram08.pdf)

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.

Fee for Service Research by QH Clinical and Statewide Services (CaSS)

**NOTE: For Qld Health – the delegated authority to sign ALL contracts is the responsibility of the District CEO or delegate.**

## 11. Intellectual Property considerations

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

Yes  No

11.2 Has a search of patent databases been undertaken?

Yes  No

Step by step assistance on searching patent databases is available in IP Fact sheet 1 titled "Information for Medical Researchers" at:

[http://www.health.qld.gov.au/ohmr/html/rcpu/intel\\_prop.asp](http://www.health.qld.gov.au/ohmr/html/rcpu/intel_prop.asp)

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

11.4 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 11.1 and 'no' to 11.2 and/or 11.3 and/or 11.4 then you should take the following steps:

- (iii) 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
- (iv) 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.

## 12. 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. If "yes" is ticked below, appropriate documentation of approval must be attached or forwarded to the site's Research Governance Officer when available.

12.1. 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  Attached  No

12.2. Is committee approval of chemical safety required (drugs/pharmacy committee)? Yes  Attached  No

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

12.4. Will the project require application for a licence to the NHMRC Licensing Committee to conduct embryo research? Yes  No

12.5. 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? Yes  No  N/A

### 13. 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 equivalent) in the first instance before final authorisation by the District CEO or delegate.*

#### **13.1 Departments and services involved in research \***

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

<b>Department/location (e.g. Pathology, Allied Health)</b>	<b>Name of responsible person</b>
Research, Ethics and Governance Office	Mr Ima Wiseman
Mental Health Services	Dr Serene

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

#### **13.2 Study Budget - at this site**

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

### 13.5 Site Finance Management

Item/s	Monetary cost for the site \$	Per participant costs \$	Funds source (Cost centre)	Cost covered by sponsor or funder (Y/N)
Supply of drugs and or other therapies.				
Radiology				
Pathology				
Pharmacy				
Diagnostics - other				
Principal Investigator	In kind support			No – approved under normal department work time
Co investigator(s)	In kind support			No – approved under normal department work time
Clinical study coordinator				
Administrative support	\$40,000.00			Yes
Other Infrastructure e.g. computers, printing, office space, stationary etc.	\$5000.00			Yes
Use of equipment				
Patient Travel & Accommodation Costs				
Staff Travel & Accommodation Costs				
Archiving				
Other (Data analysis)	\$5000.00			
<b>Total</b>	<b>\$50,000.00</b>			

**Add additional lines as required**

**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.

### 13.6 Finance Authorisation

Costs allocations and sources have been agreed:

Henry Richman	.....	.....
Director of Finance / delegate name	Director of Finance / delegate signature	Date
Annabella Pitt	.....	.....
Principal Investigator name	Principal Investigator signature	Date

## 14. 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.

### 14.1 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):

**For industry sponsored/CRO clinical trials provide the following details:**

### 14.2 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:

### 14.3 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:

**14.4** 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 Trial Coordinator has a cost centre set up for this project.

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

CO 124879					
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general research study example

**15. Declarations**

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

(Automatically populated)

**HREC Application Reference number: HREC/09/QPCH/775**

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

**Principal Investigator/Site Coordinator (s): NEAF 2.1 Ms Annabella Pitt**

- 12. 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.
- 13. I will only start this research project after obtaining authorisation from the site and approval from the responsible Human Research Ethics Committee (HREC);
- 14. 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 ICH GCP**.
- 15. 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.
- 16. I undertake to conduct this research in accordance with relevant legislation and regulations.
- 17. I agree to comply with the requirements of adverse or unexpected event reporting as stipulated by the HREC and NHMRC
- 18. I will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements.
- 19. 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.
- 20. 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.
- 21. 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.
- 22. 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 N.A.....

Signature .....Date .....

Print name of Associate Investigator Ms Matilda Money Penny.....

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.

(Automatically populated)

HREC Application Reference number: HREC/09/QPCH/775

Project Title (in full): NEAF 1.1 *“Provision of Support Services to the Novice Researcher – Does it impact Research Outcomes?”*

Principal Investigator/Site Coordinator: NEAF 2.1 Ms Annabella Pitt

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.....:

Name of Head of Department / delegate.....

Signature ..... Date .....

Name of Department.....:

Name of Head of Department / delegate.....

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.

(Automatically populated)

**HREC Application Reference number: HREC/09/QPCH/775**

**Project Title (in full): NEAF 1.1 "Provision of Support Services to the Novice Researcher – Does it impact Research Outcomes?"**

**Principal Investigator/Site Coordinator: NEAF 2.1 Ms Annabella Pitt**

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;
- 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:

**Name** .....

**Department** ..... **Position** .....

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

## 16. 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.

HREC Application Reference number: HREC/09/QPCH/775
Project Title (in full): NEAF 1.1 <i>“Provision of Support Services to the Novice Researcher – Does it impact Research Outcomes?”</i>
Principal Investigator/Site Coordinator: NEAF 2.1 Ms Annabella Pitt

	Person Completing Form Yes:No:N/A	Office Use Only Yes:No:N/A
Has a CV been attached for each researcher (or on file)?		
Have you attached proof of Professional Medical Registration (or on file)?		
Has a contact person for this research project been nominated?		
Have you completed all financial details?		

Has a copy of the HREC approval letter been provided?		
Has a copy of the final approved NEAF form been provided?		
Has a copy of the protocol been provided?		
Has a copy of the Investigator’s Brochure/drug information/device information been provided?		
Are all Participant Information and Consent Form(s) attached and show the name of the Institution and contact details of the Principal Site Investigator? <u>The version number, standard organisation name and date should be in the footer.</u>		
Has a copy of advertising been provided?		
Has a copy of any questionnaires been provided?		
Has a copy of any other document, which will be given to research participants been provided? Eg: identification card, patient diary		

If a clinical trial, are CTN/CTX forms, <b>signed</b> by the approving HREC and Principal Site Investigator attached?		
Is the Medicines Australia Standard <i>Indemnity Form</i> , <b>signed</b> by the sponsor, attached?		
Is evidence of adequate insurance cover attached?		
Is the <u>relevant</u> Medicines Australia or Queensland Health Standard Study <i>Agreement(s)</i> , <b>signed</b> by the sponsor, attached?		
If not using the Medicines Australia or Queensland Health contract is the relevant documentation <b>signed</b> and attached?		

Has evidence of Biosafety approval been provided?		
Has committee approval of chemical safety been provided (pharmacy/drug)?		
Has evidence of an application for NHMRC Cellular Therapies Advisory Committee (CTAC) been provided?		

Has evidence of an application for a licence to the NHMRC Embryo Research Licensing Committee to conduct embryo research, been provided?		
Has evidence of Radiation Safety approval been provided?		
Have you included any other site-specific policy documents required by the Institution(s) at which you intend to conduct your research? <i>Example Approval under the Public Health Act 2005 to access confidential health information for the purposes of research</i>		

Has the Resource and Budget Information Section completed?		
Has Director of Finance or delegate authorised funds (if required)?		
Is a "Declaration by Principal Investigator" signed and attached?		
Is a "Declaration by Head/s of Department" signed and attached?		
Is a "Declaration by Head of Supporting Department" signed and attached for each supporting Department (if applicable)?		
Are all pages (including attachments) numbered and dated in the footer?		

**FORWARD YOUR COMPLETED SSA AND A COPY OF YOUR HREC APPROVAL TO THE SITE/DISTRICT RESEARCH GOVERNANCE OFFICE/R**

general research study example

**17. Recommendation by RGO and sign off by District CEO**

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

<b>HREC Application Reference number: HREC/09/QPCH/775</b>
<b>Project Title (in full): NEAF 1.1 "Provision of Support Services to the Novice Researcher – Does it impact Research Outcomes?"</b>
<b>Principal Investigator/Site Coordinator: NEAF 2.1 Ms Annabella Pitt</b>

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

SSA authorisation is:

Recommended	<input type="checkbox"/>
Not recommended	<input type="checkbox"/>
Requires Chief Executive/delegate consideration	<input type="checkbox"/>

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

<p style="text-align: center; opacity: 0.5; font-size: 2em;">Research study example</p>
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Delegated Research Governance Office/r .....
Signature ..... Date.....

**(f) Authorisation by District CEO or delegate**

**HREC Application Reference number: HREC/09/QPCH/775**

**Project Title (in full): NEAF 1.1 "Provision of Support Services to the Novice Researcher – Does it impact Research Outcomes?"**

**Principal Investigator/Site Coordinator: NEAF 2.1 Ms Annabella Pitt**

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 .....**