o Site Specific Assessment Form (SSAF)

Site-Specific Assessment (SSA) Form

- *This form must be completed by the Principal Investigator responsible for the research project at this site.*
- *The completed form must be forwarded to the site's Research Governance Officer for authorisation and the signature of the Chief Executive/or delegate.*

SSA is a component of research governance and involves assessment of the suitability of the site and the Investigator(s) for the proposed research.

1. Project details

HREC Application Reference Number:

Name/ID of HREC reviewing the research project:

Project Title (in full):

2. Project summary

Provide a brief description (half page) of the project details to enable the research governance officer to understand the nature and impact of the research project at the research site.

3. Research Personnel (at your site only)

Provide details of researchers' qualifications, expertise/skills and experience in areas related to the research project.

Principal Investigator

Title:
First name:
Surname:
Mailing address:
Suburb/Town:
State:
Post code:
Organisation Name:
Position:
Business phone number:
Fax number:
Email address:
Qualifications:
Expertise:
Experience:
Role in research project:
Department:
Is evidence of current Professional Medical Registration attached? Yes ☐ No ☐ N/A ☐
(Not applicable in NSW and Queensland)
Is a *Curriculum Vitae* attached (2 page maximum). Yes ☐ No ☐ N/A ☐

Associate Investigator

Title:
First name:
Surname:
Mailing address:
Suburb/Town:
State:
Post code:
Organisation Name:
Position:
Business phone number:
Fax number:
Email address:
Qualifications:
Expertise:
Experience:
Department:
Role in research project:
Is evidence of current Professional Medical Registration attached? Yes ☐ No ☐ N/A ☐
(Not applicable in NSW and Queensland)
Is a *Curriculum Vitae* attached (2 page maximum). Yes ☐ No ☐ N/A ☐

[Copy and paste more boxes as required]

Contact person for this research project
Title:
First name:
Surname:
Mailing address:
Suburb/Town:
State:
Post code:
Organisation Name:
Position:
Department:
Business phone number:
Mobile number:
Fax number:
Email address:

4. Training

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

Yes ☐ No ☐

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

Researcher	**Training required**	**Who will provide training?**

[Insert more rows as required]

5. Recruitment of Participants

What is the proposed number of participants to be recruited at this site?

6. Participant details

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

7. What additional time and resources above their routine duties will be required of the research team throughout the research project?

Name: Department/location: Additional time spent (hours/week):	

Name: Department/location: Additional time spent (hours/week):	
Name: Department/location: Additional time spent (hours/week):	
Name: Department/location: Additional time spent (hours/week):	

[Insert more rows as required]

8. Anticipated start and finish dates for the research project?

Start date (dd/mm/yy): Finish date (dd/mm/yy): Duration (months):

9. Departments and services involved in research.

List and specify the departments/locations involved in the research, which are part of this site.

Department/location	Name of responsible person

Note: A signed declaration from the Head of Department / organisation must be attached (see #14. Declarations). [Insert more rows as required]

10. Study budget.

An explanation of how the research project will be funded at the site must be provided to ensure adequate financial arrangements are planned. To assess the financial impact of the research any costs incurred by the organisation should be provided.

Type of funding	**Source of funding**	**Amount ($/year or $/participant)**
Commercially Sponsored		
Sponsored, other (e.g. collaborative groups)		
External funding *(e.g.NHMRC, Foundations, etc)*		
Internal/Departmental funding		

[Give details of the type and name of the funding organisation]

Other financial, material and capital support.

Infrastructure charge	
Supply of drug(s)	
Loan of equipment	
Other	

[Give details of support given]

Which organisation will receive and manage this funding and/or will be the Administering Organisation?
[Give full address for correspondence]

Organisation Name:
Details of contact person
Title:
First name:
Surname:
Position:
Department:
Mailing address:
Suburb/Town:
State:
Post code:
Business phone number:
Mobile number:
Fax number:
Email address:
Insert the account number(s)/cost centre details into which funds are to be deposited.

#……
#……

11. Site-specific policies.

For organisations that have site specific policies.
(e.g. Wording related to the use of contraception in participant information and consent documents.)
This must not be used by the site to require re-review of the consent documents by the local HREC

Does the research comply with site-specific policies/requirements?
Yes ☐ No ☐

If no, please give an explanation.

12. Clinical trials information.

If the study is a clinical trial the following sections must be completed.

Is the research project being conducted under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes?

Yes ☐ No ☐

If yes, attach the relevant TGA Form to this form.

See Standard Operating Procedures.

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)

Is evidence of adequate insurance cover attached?

Yes ☐ No ☐ N/A ☐

(If no or N/A please give an explanation)

Is the Medicines Australia Standard Clinical Trial Agreement(s), signed by the sponsor attached?

Yes ☐ No ☐ N/A ☐

(If no or N/A please give an explanation)

13. Biosafety, chemical and radiation safety

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.

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 ☐

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

3. Will the project require NHMRC Gene and Related Therapies Research Advisory Panel (GTRAP) assessment? Yes ☐ No ☐

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

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 ☐

See Standard Operating Procedures for additional details.

14. Declarations

(a) Declaration by the Principal Investigator and Associate Investigator(s)

HREC Application Reference number:

Project Title (in full):

Principal Investigator:

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 Ethical Conduct in Human Research.*

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 research governance officer 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, research governance officer, 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 HREC, research governance officer, 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.

Signature of Principal Investigator ……..

Print name …… Date ……

Signature of Associate Investigator ……

Print name …… Date ……..
[Copy and paste more Signatures of Associate Investigator as required]

(b) Declaration by Head of Department and Stream Leader where the Principal Investigator will do the research.

HREC Application Reference number:

Project Title (in full):

Principal Investigator:

I certify that I have read 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.

I certify that all researchers/students from my Department involved in the research project have the skills, training and experience necessary to undertake their role.

I certify that there are suitable and adequate facilities and resources for the research project to be conducted at this site.

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

Name of Head of Department (or appropriate person): ……

Name of Department (or relevant section): ……

Signature …… Date ……

Print name ……..

*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.

Name of Stream Leader: ……

Signature …… Date ……

Print name ……..

(c) Declaration by Head of Supporting Department(s)

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

HREC Application Reference number:
Project Title (in full):
Principal Investigator:

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 …… Date ……

Signature ……..

Department ……

[Copy and paste for each Department providing service)

(d) Declaration by the Authority for Data Provision

This form is to be completed by the person authorised to provide data services for research projects.

HREC Application Reference number:

Project Title (in full):

Principal Investigator:

I have considered this proposal and consulted the appropriate personnel and I confirm that I have seen all relevant documents that are required. The Department(s) is (*tick whichever applies*):

☐ able to confirm that the data services indicated will be provided, within the present resources;

☐ able to confirm that the data services indicated will be provided, if the following financial assistance is provided:

☐ unable to provide data services indicated, on the following grounds:

I certify that I will give due regard to any ethical conditions imposed by the approving HREC when deciding whether, and in what form, I will release data to the investigator.

Name …… Date ……

Position ……

Signature ……..

Department ……

(e) General Managers Signature

The General Manager is required to certify that the attached application satisfies all the requirements of the institution. This requires:

1 Assessment of the medical/clinical appropriateness of the research study being conducted in the Health Service or on Health Service patients/clients.

2 Assurance that the study is adequately resourced in terms of staffing, facilities and funding and that there will not be an adverse impact on services provided by the Health Service.

Certification to this effect by the Stream Leader and Department Manager is required before consideration by the General Manager. In addition, this form should be signed by any other Departmental Managers whose departments may be required to contribute resources to the research project (eg Clinical Information, diagnostic services or pharmacy). If these signatories have any concerns, the General Manager will take these into account, before endorsing the application and may reject the application.

HREC Application Reference number:

Project Title (in full):

Principal Investigator:

Certification by General Manager:

Certification is needed to indicate agreement that resources, included staff time, pathology etc, from the hospital or area service unit can be utilised for the research as detailed in the application form and protocol. If resources of a number of hospitals within the SSWAHS (Western Zone) are to be utilised, certification by each General Manager is required.

I certify that this request satisfies all the requirements of this Institution and/or Service.

Name: (General Manager of ..... Hospital)
(Please print)

Signature: _____ Date: _____

(f) Recommendation by the Research Governance Office

HREC Application Reference number:
Project Title (in full):
Principal Investigator:

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

SSA authorisation is: Recommended ☐

Not recommended ☐

Requires Chief Executive/delegate consideration ☐

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

Research Governance Officer (or equivalent)

Name ……..

Signature …… Date ……

(g) Authorisation by Chief Executive (or delegate)

HREC Application Reference number:

Project Title (in full):

Principal Investigator:

This research is: authorised ☐ not authorised ☐

Specify, conditions applying to authorisation or reasons for not authorising.

My signature indicates that I authorise/ do not authorise this research project to commence at this site.

Signature …….. Date ……..

Name of Chief Executive (or delegate): ……..

Name of Organisation ……..

Checklist

Please complete the checklist with Yes: No: NA (Not Applicable). Include this checklist with the SSA Form.

HREC Application Reference number:
Project Title (in full):
Principal Investigator:

	Person Completing Form **Yes:No:NA**	Office Use Only **Yes:No:NA**
Has a CV been attached for each researcher?		
Have you attached proof of Professional Medical Registration? (NA in NSW and Queensland)		
Has a contact person for this research project been nominated?		
Have you completed all financial details in #10?		

Has a copy of the HREC approval letter been provided?		
Has a copy of the ethics application 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? The version number, standard organisation name and date should be in the footer.		
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, **signed** by the approving HREC and Principal Site Investigator, attached?		
Is the Medicines Australia Standard Indemnity Form, **signed** by the sponsor, attached?		
Is evidence of adequate insurance cover attached?		
Is the Medicines Australia Standard Clinical Trial Agreement(s), **signed** by the sponsor, 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 Gene Related Therapies assessment been provided?		
Has evidence of an application for a licence to the NHMRC 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?		

Is a “Declaration by Principal Investigator” signed and attached?		
Is a “Declaration by Head of Department” signed and attached?		
Is a “Declaration by Head of Supporting Department” signed and attached for each supporting Department (if applicable)?		
Is a “Declaration by the Authority for Data Provision” signed and attached (if applicable)?		
Are all pages (including attachments) numbered and dated in the footer?		