



Site Specific Assessment (SSA) Form

Fiona Stanley Hospital

1. Project Details

1.1 Project

1.1.0 PRN:	RGS0000000055
1.1.1 Project title:	Research Governance Service Test Project 1.1.
1.1.2 Short title:	RGS Test 1
1.1.3 Acronym:	RGST1
1.1.4 Protocol number:	V1.0 Date 01/02/2017
1.1.5 Protocol version number:	1.00
1.1.6 Protocol version date:	01/02/2017
1.1.7 Coordinating Principal Investigator:	Katherine Coltrona

1.2 Scientific and Ethical Review

1.2.1 Reviewing HREC:	Royal Perth Hospital HREC (EC00270) and Department of Health WA Human Research Ethics Committee (EC00422)
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Submit the HREC approval letter with your application.

1.2.2 Single-centre or multi-centre project:	Multi-centre
1.2.3 Jurisdictions where project will be conducted within Australia:	Inter-jurisdictional (across Australia)
1.2.4 Type of ethical review:	WA Health single ethical review
1.2.5 Risk type:	More than low risk

1.3 Project Site(s)

1.3.1 Nominate the sites involved with conducting the project, to which this SSA form applies:	Fiona Stanley Hospital
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1.3.2 Number of Sites Involved with the Project

1.3.2.1 Number of sites - WA Health sites:	5
1.3.2.2 Number of sites - Non-WA Health sites within WA:	2
1.3.2.3 Number of sites - Non-WA sites within Australia:	1
1.3.2.4 Number of sites - Non-Australian sites:	10

1.4 Project Summary

1.4.1 Project Summary:	Text here.
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1.5 Anticipated Start and Finish Dates for the Research Project at the Site(s)

1.5.1 Start date:	01/04/2017
1.5.2 Finish date:	01/04/2021
1.5.3 Duration:	4 year(s)

2. Broad Research Area, NHMRC Group and Field of Research

2.1 Broad research area: Clinical medical and science research

2.1.2 Clinical medical and science research type: Clinical trial - drug, Clinical trial - device, Clinical trial - surgery & other procedural intervention, Clinical trial - other, Clinical data registry, Clinical interventional research other than clinical trials, Clinical non-interventional research

2.2 NHMRC Group and Fields of Research

2.2.1 NHMRC group: CARDIOVASCULAR MEDICINE AND HAEMATOLOGY, CLINICAL SCIENCES

2.2.2 NHMRC fields of research: Cardiology (incl. Cardiovascular Diseases), Haematology, Respiratory Diseases, Cardiovascular medicine and Haematology nec , Anaesthesiology, Clinical Chemistry (diagnostics), Clinical Microbiology, Dermatology, Emergency Medicine, Endocrinology, Gastroenterology and Hepatology, Geriatrics and Gerontology, Infectious Diseases, Intensive Care, Medical Genetics (excl. Cancer Genetics), Nephrology and Urology, Nuclear Medicine, Orthopaedics, Otorhinolaryngology, Pathology, Physiotherapy, Podiatry, Psychiatry (incl. Psychotherapy), Radiology and Organ Imaging, Rehabilitation and Therapy (excl. Physiotherapy), Rheumatology and Arthritis, Surgery, Venereology, Clinical Sciences not elsewhere classified

3. Investigators - Fiona Stanley Hospital

Role	Name	Qualifications and Expertise Relevant to the Project	GCP Certified	Student?	Name and Location of Student Supervisor	Site(s) for Which the Investigator Is Responsible
PI	Ms Katherine Coltrona Department of Health	Text here.	Yes	Yes	Text here.	Department of Health, Fiona Stanley Hospital, Fremantle Hospital Health Service, Rockingham General Hospital, Royal Perth Hospital

3.3 Conflict of Interest

3.3.1 Have any of the investigators involved with the project site have a conflict of interest to declare?

Yes

Name	Role(s)	Status	Date Signed
	CPI, PI	Submitted	01/03/2017

3.4 Site Contact Person

3.4.1 Contact person:

Name: Ms Katherine Coltrona

Address: Level 2, C Block 189 Royal Street East Perth Western Australia Australia 6004

Organisation: Department of Health

Department: Clinical Services and Research | Office of the Chief Medical Officer

Position: Senior Policy Officer

Phone (business): 08 9222 4332

Mobile: 0400 123 456

Email: katherine.coltrona@health.wa.gov.au

4. Credentialing and Training

4.1 Is there any relevant certification, accreditation or credentialing requirements relevant to the conduct of this research?

Yes

4.1.1 Describe the certification, accreditation or credentialing requirements e.g. phlebotomy, IATA training for transporting biological samples: Text here.

4.1.2 Will any of the investigators or research personnel at the site(s) require extra training or credentialing to enable their participation in the project? Yes

4.1.2.1 Research personnel:

Training/credentialing required: Text here.

Who will provide training/credentialing? Text here.

5. Participants

5.1 Participants Details for the Site(s)

5.1.1 What is the expected number of participants for each WA Health site covered by this SSA form?

Site	Number of Participants
Fiona Stanley Hospital	5

5.1.2 Where will the participant's project visits/follow-up occur (venue)? Text here.

5.2 What Categories of People Will Participate in Research?

5.2.1 People whose primary language is other than English (LOTE): Primary intent of research

5.2.2 Women who are pregnant and the human fetus: Primary intent of research

5.2.3 Children and/or young people (i.e. < 18 years): Primary intent of research

5.2.4 People in existing dependent or unequal relationships: Primary intent of research

5.2.5 People highly dependent on medical care: Primary intent of research

5.2.6 People with a cognitive impairment, an intellectual disability or a mental illness: Primary intent of research

5.2.7 Aboriginal people: Primary intent of research

5.2.8 People who may be involved in illegal activity: Primary intent of research

5.2.9 People in other countries: Primary intent of research

5.3 Recruitment Process

5.3.1 Process used to identify potential participants for the project at the site(s): Text here.

5.3.2 How initial contact will be made with potential participants at the site(s): Text here.

6. Department of Health WA Data Collections or Data Linkage

6.1 Does the project require access to confidential information from Department of Health data collections or data linkage? Yes

6.1.1 Have the Data Custodian or Data Linkage Branch Project Officer been consulted regarding access to confidential information held by the Department of Health, to determine whether the data required is collected and accessible?

No

If No, consult with the relevant Data Custodian or with the Data Linkage Branch Project Officer to discuss the requirements before applying for the data or requesting Department of Health WA HREC approval. Consultation with the appropriate data managers will be arranged following submission of an Expression of Interest (EOI) for Data, available on the Application for Data Form.

7. Coronial Post Mortem Material

7.1 Does the project require access to coronial post mortem material?

Yes

7.2 Has the project received approval from the Coronial Ethics Committee (WA)?

Yes

8. Adults with an Impaired Capacity or Who Are Unable to Consent

8.1 Will the project involve adults with an impaired capacity or who are unable to consent?

Yes

9. Aboriginal People

9.1 Does the project involve Aboriginal people in the categories that require WAAHEC approval?

Yes

9.1.1 Has the project received approval from WAAHEC?

Yes

10. Children and/or Young People (i.e. < 18 Years)

10.1 Does the research project involve direct contact with children?

Yes

10.1.1 Have all research personnel who will be coming in contact with the paediatric participants obtained a Working with Children licence and has it been sighted by their Manager?

No

10.1.1.1 Explain why it is not necessary:

Text here.

11. Clinical Trials

11.1 Clinical trial phase

Phase 0 clinical trial, Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV / post-marketing surveillance

11.2 Product name(s)

Text here.

11.3 Research Conducted Under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) Schemes

11.3.1 Conducted under clinical trial notification (CTN) or exemption (CTX) scheme:

Clinical trial notification

11.3.2 CTN/CTX TGA ID Number:

Text here.

11.4 Clinical Trials Registry

11.4.1 Registered on a publicly accessible clinical trials registry database:

Yes

- 11.4.1.1 Clinical trial registry name: Other
- 11.4.1.1.1 Other registry name: Text here.
- 11.4.1.2 Clinical trial registry reference number: Text here.

12. Indemnity and Insurance

12.1 Clinical Trials

- 12.1.1 Commercial or non-commercial clinical trial: Non-commercial
- 12.1.1.2 Does the non-commercial trial involve an external entity? Yes
- 12.1.1.2.1 If the project is a non-commercial clinical trial involving WA Health and an external entity, will both parties be responsible for their own liabilities? Yes
- 12.1.1.2.1.1 Is evidence of adequate and current insurance cover required? Yes

13. Research Agreements

- 13.1 Is a research agreement with an external organisation required? Yes
- 13.1.1 Agreement type: Clinical Trial Research Agreement – Medicines Australia – Standard Form (Form A), Clinical Trial Research Agreement – Standard Form B – For studies involving a sponsor and a contract research organisation (Form B), Clinical Trial Agreement – Collaborative or Cooperative Research Group (CRG) Studies – Standard Form (Form C), Clinical Trial Research Agreement – Medicines Australia Form: Contract Research Organisation acting as the Local Sponsor (Form D), Clinical Trial Research Agreement – Phase IV Clinical Trial (Form E), MTAA Standard Clinical Investigation Research Agreement (CIRA), WA Health Confidentiality Agreement, Material Transfer Agreement, Funding Agreement, Service Agreement – WA Health providing the service, Service Agreement – WA Health receiving the service, Other (non-standard research agreement)
- 13.1.2 Is there a previously agreed research agreement with the external organisation? Yes
- 13.1.3 Name of organisation(s) entering into the written agreement with WA Health: Text here.
- 13.1.4 Has the non standard research agreement been reviewed and approved by WA Health Legal and Legislative Services prior to this application? Yes

14. Intellectual Property

- 14.1 Is there a possibility of significant new Intellectual Property being developed from the project? Yes
- 14.1.1 Is there an agreement stating arrangements for the use of existing intellectual property and the parties' rights in relation to ownership? Yes
- 14.1.2 Is there an agreement stating arrangements for the use of all new intellectual property developed through the research project? Yes

15. Biosafety, Chemical and Radiation Safety

- 15.1 Indicate if the project involves any of the following project specific requirements: Human genetic technologies, Human embryos or gametes

15.2 Human Genetic Technology

15.2.1 Does the Institutional Biosafety Committee (IBC) require notification of the project and/or is a licence related to genetically modified organisms required from the Office of the Gene Technology Regulator (OGTR)?

Yes

15.3 Human Embryos or Gametes

15.3.1 Does the project require a licence from the NHMRC Licensing Committee to conduct embryo research?

Yes

15.3.2 Does the project require Reproductive Technology Council approval?

Yes

15.4 Ionising Radiation

15.4.1 Does the project involve the exposure of participants to ionising radiation (including normal standard of care)?

Yes

15.4.2 Is the exposure of ionising radiation additional to the research participant's normal standard of care?

Yes

15.4.2.1 If exposure is additional to normal standard of care, has the institutions' Medical Physicist reviewed the project in accordance with the ARPANSA/Radiological Council guidelines and prepared a dosimetry report?

Yes

15.4.2.2 Is Radiological Council approval required?

Yes

15.4.3 Will any use of off-site facilities be utilised for imaging services?

Yes

If off-site facilities are used, the PI must complete the budget and declarations section for the offsite supporting department.

16. Resource and Budget Information

16.1 Will participants receive any payment or expenses for participation in the research?

Yes

16.1.1 Provide details

Text here.

17. Funds Management Details

Funder Organisation Name	Funder Organisation Type	ABN	Major Funder?
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17.1 External Funder Organisation Contact Details

Name: Mr Joe Bloggs

Address:

Organisation: LL UAT University ABC

Department:

Position: Finance Officer

Phone (business): 9999 9999

Mobile:

Email:

17.2 WA Health Account Details

17.2.1 WA Health cost centre and account details:

Text here.

18. Declarations

18.1 Declaration by All Responsible Principal Investigators

1. I declare the information in this form is truthful and accurate to the best of my knowledge and I take full responsibility for the project at my nominated site(s).
2. I certify that I and all members of the research team have the appropriate qualifications, training, experience and facilities to conduct the research set out in the attached application and to deal with any emergencies and contingencies related to the research that may arise.
3. I will only start this research project after obtaining authorisation from the site, which will include approval from the responsible Human Research Ethics Committee (HREC).
4. I accept responsibility for the conduct of this research project according to the principles of the most current versions of the NHMRC National Statement on the Ethical Conduct in Human Research, Australian Code for the Responsible Conduct of Research and Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95).
5. I undertake to conduct this research project in accordance with the HREC's conditions of approval and the requirements of site authorisation by the organisation(s) involved.
6. I undertake to conduct this research in accordance with relevant legislation, regulations and the WA Health Research Governance Policy and Procedures.
7. I agree to comply with the HREC's and site's monitoring requirements including adverse or unexpected event reporting.
8. I will inform the HREC and the site if the research project ceases before the expected date. I will discontinue the research if the HREC withdraws ethical approval.
9. I understand and agree that project files and documents and research records and data may be subject to inspection by the HREC, site, the sponsor or an independent body for audit and monitoring purposes.
10. I understand that information relating to this research, and about me as an investigator, will be held by the HREC, site and on the WA Health Research Governance Service (RGS). This information will be used for reporting purposes and managed according to the principles established in the Privacy Act 1988 (Cwlth) and relevant laws in the States and Territories of Australia.

The Budget Form must be completed and authorised before submitting the SSA Form to the Business Manager and Divisional Director for authorisation.

Name	Position	Signature	Date
Katherine Coltrona	PI	Signed	19/12/2017

18.2 Declaration by All Responsible Business Managers, Divisional Directors and Regional Directors

In addition, for WACHS a declaration from the relevant **Regional Director** is required.

1. I certify that I have read the research project details covered by this form and that the research is appropriate to be conducted within this Department and at the site(s).
2. I certify that there are suitable and adequate facilities, resources and funding for the research project to be conducted at the site(s).
3. My signature indicates that I support this research project being carried out using such resources and funding, as documented in the Budget Form associated with this form.

Name	Position	Signature	Date	Invitation Status	Select
Alexandra Coltrona	Business Manager - Fiona Stanley Hospital	Signed	19/12/2017	Accepted	
Rachael Coltrona	Divisional Director - Fiona Stanley Hospital	Signed	19/12/2017	Accepted	