



# WA Health Ethics Application Form

## 1. Introduction

### 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

1.1.4.1 Protocol number: V1.0 Date 01/02/2017

1.1.4.2 Protocol version number: 1.00

1.1.4.3 Protocol version date: 01/02/2017

1.1.5 Project summary: Text here.

### 1.2 Sites

1.2.1 Number of sites - Australia: 8

1.2.2 Number of sites - Non-Australian sites: 10

1.2.3 Site names within Australia in RGS: Department of Health, Royal Perth Hospital, Fiona Stanley Hospital, Rockingham General Hospital, Fremantle Hospital Health Service

1.2.4 Other site names: SJOGH; Mercy Hospital; Monash University;

### 1.3 Scientific and Ethical Review

1.3.1 Reviewing HREC: Royal Perth Hospital HREC, Department of Health WA Human Research Ethics Committee

1.3.2 Single-centre or multi-centre project: Multi-centre

1.3.3 Sites under approval - name of the site(s) which will rely on the ethical approval from the nominated HREC(s) for this application: Department of Health, Royal Perth Hospital, Fiona Stanley Hospital, Rockingham General Hospital, Fremantle Hospital Health Service

1.3.4 Risk type: More than low risk

1.3.5 Is this project being submitted to (or has it been previously submitted to) another Australian HREC? Yes

1.3.6 How many Australian HRECs will the research proposal be submitted to? 5

1.3.7 Provide the Australian HREC's name, approval status and details of any required amendments or conditions of approval:

HREC	Status	Condition of Approval
Mount Hospital Ethics Committee (EC00387)	Not approved	N/A
St John of God Health Care Human Research Ethics Committee (EC00286)	Not approved	N/A
Monash Health Human Research Ethics Committee A (EC00382)	Not approved	N/A
Department of Health WA Human Research Ethics Committee (EC00422)	Not approved	N/A

HREC	Status	Condition of Approval
Royal Perth Hospital Human Research Ethics Committee (EC00270)	Not approved	N/A

## 1.4 Academic/Scientific Review

1.4.1 Has the research project undergone a peer review process?

Yes

1.4.2 Provide details of the review and the outcome:

Text here.

## 1.5 Consumer and Community Review

1.5.1 Has the project involved consumer or community input or review?

Yes

1.5.2 Describe this engagement:

Text here.

## 1.6 Resources

1.6.1 Indicate how the project will be/or is intended to be funded or supported in-kind. Provide an estimate of the total for all sites covered by this ethics application form:

Funder Organisation Type (For All Sites)	Funder Organisation Name	Estimate \$ Amount of Any Funding (For All Sites)	Estimate \$ Amount of Any In-kind-support (For All Sites)	Funding is Confirmed / Received or Being Sought
Government - state (WA)	Department of Health	\$0.00	\$3,000.00	Confirmed
University	LL UAT University ABC	\$10,000.00	\$0.00	Confirmed
Government - state (WA)	Fiona Stanley Hospital	\$0.00	\$3,000.00	Confirmed
Government - state (WA)	South Metropolitan Health Service Executive	\$0.00	\$3,000.00	Confirmed
Government - state (WA)	Royal Perth Hospital	\$0.00	\$5,000.00	Confirmed
Sub total		\$10,000.00	\$14,000.00	

Total funding/in-kind support for all sites: \$24,000.00

1.6.2 How will a funding shortfall (if any) be met?

N/A

1.6.3 Is this a project where capitation payments are to be made?

Yes

1.6.4 Will participants be made aware of these payments to research personnel?

Yes

1.6.5 Explain how this will be done:

Text here.

## 2. Project Team

### 2.1 Investigators

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
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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
CPI PI	Ms Katherine Coltrona Department of Health Clinical Services and Research   Office of the Chief Medical Officer  Senior Policy Officer katherine.coltrona@health.wa.gov.au	Text here.	Yes	Yes	Text here.	CPI: All PI: Department of Health, Fiona Stanley Hospital, Fremantle Hospital Health Service, Rockingham General Hospital, Royal Perth Hospital

## 2.2 Disclosure of Interest

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

Yes

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

## 2.3 Contact Person

2.3.1 Contact person for this project:

**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

## 3. Project Details

### 3.1 Background

3.1.1 Summary of findings from previous projects and references to literature and data relevant to the project:

Text here.

3.1.2 Product name(s):

Text here.

### 3.2 Aims and Significance

3.2.1 Aims, objectives:

Text here.

3.2.2 Hypothesis:

Text here.

3.2.3 Significance, justification and relevance to current research:

Text here.

3.2.4 Expected benefits to the participant and community. Potential contribution to knowledge, treatment, disease prevention, health promotion or social improvement:

Text here.

3.2.5 Actual and potential risks to participants and mitigation of risks:

Text here.

### 3.3 Methodology

- 3.3.1 Research type and design: Text here.
- 3.3.2 Source and selection of participants/data: Text here.
- 3.3.3 Treatment of participants: Text here.
- 3.3.4 Assessment of efficacy: Text here.
- 3.3.5 Assessment of safety: Text here.
- 3.3.6 Data management, statistical analysis and record keeping: Text here.

### 3.4 Project Duration

- 3.4.1 Expected start date: 01/04/2017
- 3.4.2 Expected finish date: 01/04/2021
- 3.4.4 Duration: 4 year(s)

## 4. Participants

### 4.1 Source and Number

- 4.1.1 Provide the age range and source of participants, their tissue or data: Text here.
- 4.1.2 What is the expected total number of participants in this project at all Australian sites? 100
- 4.1.3 What is the expected number of participants for each WA Health site involved with the project?

Site	Number of Participants
Department of Health	5
Royal Perth Hospital	5
Fiona Stanley Hospital	5
Rockingham General Hospital	5
Fremantle Hospital Health Service	5

### 4.2 What Categories of People Will Participate in Research?

- 4.2.1 People whose primary language is other than English (LOTE): Primary intent of research
- 4.2.2 Women who are pregnant and the human fetus: Primary intent of research
- 4.2.3 Children and/or young people (i.e. < 18 years): Primary intent of research
- 4.2.4 People in existing dependent or unequal relationships: Primary intent of research
- 4.2.5 People highly dependent on medical care who may be unable to give consent: Primary intent of research
- 4.2.6 People with a cognitive impairment, an intellectual disability or a mental illness: Primary intent of research
- 4.2.7 Aboriginal people: Primary intent of research
- 4.2.8 People who may be involved in illegal activity: Primary intent of research
- 4.2.9 People in other countries: Primary intent of research

### 4.3 Recruitment

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

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

4.3.3 Will recruitment be from small rural communities? Yes

4.3.4 Many rural communities have small populations. Explain how consideration has been given to the risk of overburdening the community with the research (in relation to other projects which may be concurrently occurring or have occurred recently) taking into account the size of community: Text here.

#### 4.4 People Whose Primary Language Is Other than English (LOTE)

4.4.1 List the main language, other than English, that the participants have as their primary language: Text here.

4.4.2 Describe the steps taken to ensure that the information provided to these participants will enable them to understand the research project and freely give consent, e.g. interpreter, translated information sheet and consent, etc. Text here.

#### 4.5 Women Who Are Pregnant and the Human Fetus

4.5.1 Describe how the research conforms to the requirements as set out in Chapter 4.1 of the National Statement: Text here.

#### 4.6 Aboriginal People

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

4.6.2 Outline how the NHMRC "Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research" 2003 have been addressed in the research: Text here.

4.6.3 Has the project received approval from WAAHEC? Yes

#### 4.7 People Who May Be Involved in Illegal Activity

4.7.1 Describe how the research conforms to the requirements as set out in chapter 4.6 of the National Statement: Text here.

#### 4.8 People in Other Countries

4.8.1 Describe how the research conforms to the requirements as set out in chapter 4.8 of the National Statement: Text here.

#### 4.9 Consent

4.9.1 Will the research involve informed consent of participants? Both yes and no

4.9.2 How will informed consent be obtained/recorded? Text here.

4.9.3 Justify why consent will not be obtained (i.e. waiver or opt-out): Text here.

- 4.9.4 Will any of the participants lack the capacity to give consent? Yes
- 4.9.5 Outline the ways in which inclusion of any such persons will be managed: Text here.
- 4.9.6 Does the research project involve limited disclosure, concealment or deception of participants? Yes
- 4.9.7 Detail why this is required and how this will be conducted: Text here.
- 4.9.8 If a participant or person on behalf of a participant chooses not to participate, are there specific consequences of which they should be made aware, prior to making this decision? Yes
- 4.9.9 Provide details: Text here.
- 4.9.10 If a participant or person on behalf of a participant chooses to withdraw from the research, are there specific consequences of which they should be made aware, prior to giving consent? Yes
- 4.9.11 Provide details: Text here.
- 4.9.12 Will a participant or person on behalf of a participant who withdraws from the research be able to withdraw data about the participant? Yes
- 4.9.13 Provide details: Text here.
- 4.9.14 Is any financial remuneration/reimbursement or other benefit being offered to participants in the project? Yes
- 4.9.15 State how much, or what, will be offered and for what purpose. Indicate whether participants will be informed of the remuneration/reimbursement and outline how this will be communicated to them: Text here.

#### 4.10 Adults with Impaired Capacity to Consent

- 4.10.1 Will the project involve adults who may have an impaired capacity to consent? Yes
- 4.10.2 Indicate the condition, disease or general reasons why participants may be incapable or require assistance to provide consent to take part in the research: Text here.
- 4.10.3 How is the proposed research not against the interests of the potential participant? Text here.
- 4.10.4 How is the use of a proposed intervention and/or medication supported by the literature or current clinical best practice? Text here.
- 4.10.5 How will the project be discussed with the substitute decision maker and how is it intended to record whether they know of any objections the proposed participant may or may not have had? Text here.
- 4.10.6 Is any reading material being provided to the substitute decision maker? Yes
- 4.10.7 How will consent be obtained if the proposed participant becomes able to give consent during the project? Text here.

4.10.8 How will the project be discussed with the proposed participant and the substitute decision maker where assistance with the consent process is required and how it is intended to record the process and document the participant's consent? Text here.

4.10.9 Is any reading material being provided to the proposed participant and the substitute decision maker in such instances? Yes

#### 4.11 Children and Young people

4.11.1 Will children be involved in this research? Yes

4.11.2 Is it intended to obtain the consent of the child? Yes

4.11.3 Investigators should document the consent discussion with both parents and child including details as to who is going to assess the capacity of the child and how this will be done. Please outline the process that will be followed: Text here.

4.11.4 If applicable, will child participants be asked to consent or re-consent at age 18 years? Yes

4.11.5 Explain how this will occur: Text here.

#### 4.12 Dependent Relationships

4.12.1 Is there any pre-existing or potential relationship between the investigators and the participants? Yes

4.12.2 Specify the nature of any existing or potential relationship, between the participants and any members of the research team or organisation involved in the research. Describe the steps, if any, will be taken to ensure that the relationship does not impair participants' free and voluntary consent and participation in the project; or does not impair any existing or foreseeable future relationship between participants and the investigators or organisation: Text here.

### 5. Methodology

#### 5.1 Project Methods

5.1.1 Indicate if the project involves any of the following methods or fields: Qualitative methods  
Quantitative methods, population level data, databanks  
Interventions and therapies, including clinical and non-clinical trials, innovations, ionising radiation  
Biospecimen analysis, including human genetic technologies, human embryos or gametes

#### 5.2 Interventional

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

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

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

5.2.4 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

5.2.5 Is Radiological Council approval required? Yes

### 5.3 Biospecimens

5.3.1 Will any samples of body fluid or body tissue be used for this project? Yes

5.3.2 If yes, indicate the type of samples: Blood,Tissue,Other

5.3.3 Other: Text here.

5.3.4 Will the project involve the use of human tissue from persons who were the subject of a post mortem? Yes

5.3.5 Are samples to be taken from a non-coronial post mortem? Yes

5.3.6 Does the project require access to coronial post mortem material? Yes

5.3.7 Have the samples been obtained previously? If both apply, indicate Yes and No: Both yes and no

5.3.8 How were the samples obtained, for what purpose was consent obtained and name the organisation and archive/bank where the tissue samples were stored: Text here.

5.3.9 How will the samples be obtained and who will collect them? Text here.

5.3.10 Will these samples be identified, and if so how? Text here.

5.3.11 What are the samples to be used for and where will sample analysis occur? Text here.

5.3.12 Where will these samples be stored? Text here.

5.3.13 How long will all samples be stored for? Text here.

5.3.14 Will samples be stored in a re-identifiable manner? Yes

5.3.15 Will participants be able to withdraw their sample and have it destroyed? Yes

5.3.16 Outline the process for withdrawing the sample: Text here.

5.3.17 Will the stored samples be used for other future research? Yes

5.3.18 Provide details: Text here.

5.3.19 How will the samples be disposed of? Text here.

### 5.4. Human Genetic Technologies

5.4.1 Does the project involve human genetic research? Yes

5.4.2 Address the relevant aspects described in the National Statement chapter 3.5 and 3.6 relevant to the proposed research: Text here.



## 5.5. Human Embryos or Gametes

5.5.1 Does the project involve assisted reproductive technology (ART)? Yes

5.5.2 If yes, describe how the research conforms to the requirements as set out in the ART guidelines: Text here.

5.5.3 Does the research include work with human embryos? Yes

5.5.4 If yes, describe how the research conforms to the requirements as set out in the ART guidelines: Text here.

## 6 Data and Privacy

### 6.1 State Data

6.1.1 Does the research collect, use, or disclose individually identifiable or re-identifiable data of a personal nature (including personal information) held in State/Territory departments or agencies e.g. medical records, hospital data bases, State based registers (cancer, genetic etc.), State Departments or other non-Commonwealth Government records? Yes

6.1.2 List all sources e.g. medical records, TOPAS, Hospital Morbidity Database: Text here.

6.1.3 Will the project involve the use of confidential information from the Department of Health data collections, data linkage and/or WA Health biobanks? Yes

6.1.4 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

*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.*

6.1.5 Does this project require approval from the Department of Health WA HREC? Yes

6.1.6 Does the project require access to coronial data or information that is held by the Office of the State Coroner (WA)? Yes

### 6.2 Commonwealth Data

6.2.1 Does the research involve access to data held by a Commonwealth Department or Agency? Yes

6.2.2 Investigators will have to comply with the privacy principles established under the **Privacy Act 1988** (Cwlth). Identify the source of the data and whether the information is being collected, used or disclosed by the Commonwealth agency: Text here.

## 6.3 Non-government Data

6.3.1 Does the research involve access to data held by a non government organisation (e.g. general practitioner, private hospital, non-government medical research institute, private university)?

Yes

6.3.2 Investigators will have to comply with the privacy principles established under **Privacy Act 1988** (Cwth). Identify the source of the data and whether the information is being collected, used or disclosed by the non-government organisation:

Text here.

## 6.4 Privacy

6.4.1 Explain why the proposed activity cannot be achieved using data which is not identifiable:

Text here.

6.4.2 Explain why it is impracticable to obtain the participant's consent:

Text here.

6.4.3 Explain why the collection, use or disclosure of this information is in the public interest, and why the public interest in the project substantially outweighs the public interest in the protection of privacy:

Text here.

## 6.5 Confidentiality

6.5.1 Explain what methods will be used to protect confidentiality/anonymity of participant data:

Text here.

## 6.6 Data Storage and Security

6.6.1 Explain how and where data will be held both during and after the project, including any arrangements for data security:

Text here.

6.6.2 Indicate how long the data will be kept:

Text here.

6.6.3 How will data be disposed of?

Text here.

## 6.7 Dissemination of Results

6.7.1 Explain when, how, where and to whom results will be disseminated e.g. a report, publication or thesis, including whether participants will be provided with information on the findings or outcomes of the project:

Text here.

## 7. Declarations

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.

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