Research Governance Service (RGS)
Research Governance Service (RGS)

- **RGS** is an information technology system developed by WA Health to support the research governance framework for conducting human research projects.

- It offers a centralised system for investigators, research group members and sponsors to complete, submit, manage and track their ethics and governance documentation through the lifecycle of their human research project. This includes approval/authorisation, monitoring and publication.

- In addition, RGS provides for Ethics, Research Governance and Hospital Administrators, Human Research Ethics Committees (and Subcommittees) to review, administer and report on all human research conducted within WA Health or accessing WA Health participants, their tissue or data.
What is the Research Governance Service (RGS)

RGS is a software application (an app)

RGS has its own security for
• the system as a whole,
• individual research projects and
• forms within the project.

RGS is hosted on the cloud

It is a web based collaborative workspace

Users can access RGS anywhere they have access to the internet anywhere in the world

RGS will run using any of the following web browsers:
• Internet Explorer 9 or higher
• Google Chrome
• Mozilla Firefox
• Safari
Who will be using the RGS

- Sponsors
- Researchers
- Organisations
- Research Governance
- HREC

Research Project
Implementation

The RGS will be implemented in 2 stages.

Why are there two stages?
It is complex and has to
• meet both State and national business and reporting requirements
• take into account WA Health’s 8 HRECs, 8 Research Governance Offices and about 157 WA Health sites
• It has to be able to allow for HREC review and approval outside of WA Health (implemented in Stage 2).

Stage 1 will be launched in November 2016 and implementation will be across all WA Health sites

Stage 2 will be a staggered releases in 2017
Stage 1

You can sign up to RGS - this is not limited to WA Health employees. CPIs can create a project workspace, add other sites and invite others to the project (including their delegate). Application forms can be completed, budgets created and supporting documents uploaded.

Submission to ethics and governance. You only need to submit something once it can be seen and reviewed those granted access.

The HREC (and subcommittees) and RGOs can review submissions. HREC approval and site authorisation for WA Health sites.

Stage 1 will meet one of the requirements of the NMA so negotiations to sign up can begin. Once signed WA Health sites can accept HREC approval from other public health certified HRECs. WA Health certified HRECs can also be a ‘Lead’ HREC for public health sites outside of WA.
Stage 2

Stage 1 will **not** involve monitoring. Monitoring forms will have to be sent to the HREC and Research Governance Offices outside the RGS until Stage 2 is implemented.

Migration of all research project from databases across WA Health into RGS.

Implementation of the monitoring of all active projects
- Amendment
- Safety Reports
- Progress Reports Annual and Final
- Complaints

Publications details will be able to be attached to research projects.

State and National reporting will be enabled
RGS & You
Research governance

The WA Health Research Governance Framework governs the scientific, ethical and governance review, approval, conduct and monitoring of human research within WA public health organisations.

Research Governance Service

The Research Governance Service (RGS), a web based information technology system, to support the WA Health research governance framework, is under development and due for completion in 2017.

Research education and training

Read more about clinical trials and research governance education

Ethics

Governance

Multi-centre research
System Requirements for RGS

RGS will run using any of these web browsers:

- Internet Explorer 9 or higher
- Google Chrome
- Mozilla Firefox
- Safari

Using RGS

Here are some ‘Tips and Tricks’ that you may find helpful in using and navigating through RGS:

- Find an answer quickly, by entering a few words in the ‘Search this site’ box found in the header of every RGS page.
- Not sure where to start? Click on a topic in the left menu that may be relevant to you, or use the Quick Start relevant to your role.
- The screens in RGS also have tooltips. Click on them to read more information about the section or field to be completed.
- Remember to refresh the page in RGS to view any recent updates. To do this, press F5 or click on the ‘Refresh’ or ‘Reload this page’ button, depending on the browser you are using.
- RGS opens a new tab in your browser when you click on a hyperlink that leads to an external website or document. You may return to your previous screen in RGS by clicking on the original tab.
- RGS uses pop ups, so please ensure your browser is allowing them. Refer to your browser’s Pop-up Blocker settings for more information.
- RGS uses your default email client when sending emails. Please ensure that the MailTo protocol of your computer is set to a valid email client (e.g. Outlook).
Welcome to the Research Governance Service (RGS)

RGS is an information technology system which supports the research governance framework for conducting WA Health human research projects.

The RGS is a centralised system for investigators, research group members and sponsors to complete, submit, manage and track their ethics and governance documentation through the lifecycle of their human research project. This includes approval/authorisation, monitoring and publication.

In addition, the service provides for Ethics, Research Governance and Hospital Administrators, Human Research Ethics Committees (and Subcommittees) to administer and report on all human research conducted within WA Health or accessing WA Health participants, their tissue or data.

Announcements

There are no items to show in this view.
Sign Up

The RGS is restricted to stakeholders conducting human research projects within WA Health or accessing WA Health participants, their tissue or data.

Prior to receiving access to the RGS, new users will be required to complete the New User Sign Up form and submit it to the RGS Administrator for approval. Approval may take 1-2 working days.

Access to the RGS will require two-step authentication, involving password entry and an additional access code sent to the user’s nominated email.

Once logged in to the RGS, the new user will have access to their own Landing Page and any Project that they are affiliated with.

RGS Account Details

Password:*  
Confirm password:*  

RGS Password Policy

• A minimum password length of any thirteen (13) characters, which could be a simple phrase;

OR

• A minimum password length of ten (10) characters that consist of at least three of the following character sets:
  1. lowercase characters (a-z)
  2. uppercase characters (A-Z)
  3. digits (0-9)
  4. special characters

Reason for requesting access to RGS:  
(choose as many roles as appropriate)

- RGS User
- Research User
- Hospital Administrator
- Committee Member
- Research Governance Officer
- Ethics Executive Officer

If you choose a role that is not appropriate to your current business role, your request will be declined and you will have to request access again.
Roles in RGS
There are a variety of roles within RGS that provide different levels of security for the users as well as for individual research projects.

RGS User – this role is assigned automatically to all users to provide basic access to the RGS.

Research User – this role includes users that intend to be involved in a research project e.g. Coordinating Principal Investigator (CPI), Principal Investigator (PI), Associate Investigator (AI), sponsors, Research Nurse, Clinical Research Coordinator.

Hospital Administrator – this role includes users who are either appointed or acting in positions that provide authorisation on site governance forms and/or budget spreadsheet; or provide site authorisation e.g. Head of Department, Business Manager, Divisional Director, Regional Director and Executive Director.

Committee Member – this role includes users who are ethics subcommittee or HREC members.

Research Governance Officer (RGO) – this role includes users who work in the WA Health Research Governance Office e.g. RGO, Governance Coordinator

Ethics Executive Officer (EEO) – this role includes users who provide administrative assistance to a WA Health HREC e.g. Ethics Secretary, Ethics Coordinator.
Local Contact within WA Health to confirm New User Details

Please provide us with the contact details of a WA Health employee that can validate your request for access to the RGS. The person you nominate will be contacted to verify your status as a researcher intending to conduct research within WA Health.

Title:* 
First name:* 
Surname:* 
Jurisdiction:* 
Region:* 
Organisation:* 
Division:* 
Department:* 
Position/Job title:* 
Primary email:* 
Phone (Business):* 
Mobile: 

I am not a robot

I have read, understood and agree with the Terms of Use and Privacy Policy

Submit  Cancel
Dear Mr Albert Macintosh,

Your request for access to the Research Governance Service (RGS) has been approved. Your RGS Account Login ID is below:

**RGS Account Login ID:**

**Roles Approved:** Research User, RGS User

You can use this Login ID, with the password you chose when creating the RGS Account, to access the RGS. You will also be sent a Unique Security Code by email (nominated by you), every time you login. Please ensure that you have access to your nominated email accounts so that you can use the security code as you will not be able to access RGS without it.

Next step is to update your Profile. You can do this now by clicking the link below (you will be required to login), or alternatively, you may update your profile at any later stage by logging in and going to the 'Update Details' page via the menu.

**RGS Update Profile Page:**

Should you require further assistance with RGS, please look at the online Help Wiki (link below). Alternatively contact the RGS Administrator on the RGS Website. You will find this information in the Contacts page.

**RGS Help Wiki:**

Regards,
The RGS Team

RGSAdmin@health.wa.gov.au
Department of Health: Research Governance Service
(http://rgs.health.wa.gov.au)

This is an automated email. Please DO NOT REPLY to this email.
A security code has been sent to your **primary email address**. Please enter the **6 digit** security code below.

If you didn't receive the security code or wish to receive a new one, please click the "Resend" button.
If you are a student

Institution: 
Course: 

Training

Provider: 
Training details: 
Date of attendance: 

Add Remove

Provider Training Details Date of Attendance Select

GCP Certificate

Choose file No file chosen Upload

Personal Documents

CV

Choose file No file chosen Upload

Save Cancel
Create a Project
Create Project

The Coordinating Principal Investigator (CPI) takes overall responsibility for conducting and monitoring a research project at all sites under the HREC’s approval. The CPI is also responsible for gaining HREC approval and will be the HREC’s primary contact for this project.

If you are not the CPI of this project, you should CANCEL this form, as it must only be completed by the CPI. If you are the CPI, click OK to proceed and your details will be recorded against the project.

Your application for a project workspace will be processed typically within 1-2 working days, and you will be contacted with the outcome once your request has been reviewed.

Note: We aim to process applications within this indicative processing time; however, actual processing time may vary depending on a range of factors.

OK  Cancel
The Administering Research Governance Office will process this form. To ensure minimal delays, it is suggested that it goes to the RGO responsible for a site where you intend to conduct the project.

WA HEALTH DECLARATION OF CONFIDENTIALITY
(for research personnel who are not WA Health employees)

GUIDELINES

The WA Health Declaration of Confidentiality must be completed by all research personnel (including students) who are not employees of WA Health, who will be:

- Conducting a research project within WA Health; or
- Accessing WA Health participants, their tissue or data.

The Declaration of Confidentiality must be completed by the non-WA Health employee for each research project they are involved with.

declaration

☐ I have read and agree to the Declaration of Confidentiality*
Thank you for your application to create a new project. Your application will be processed within 1-2 working days and you will be contacted with the outcome once your request has been reviewed.

Go back to home page
Go back to My Projects page

The new Project you requested on the Research Governance Service (RGS) has been created.

Your Project details are:

PRN: RGS0000000054
Project Title:

Protocol Number:
The new project should be visible on your landing page when you next log into the system.

As Coordinating Principal Investigator (CPI) you are responsible for any projects where you have this designation. This means that you are responsible for:

1. authorising access to your project for all Project Members (PMs); and
2. authorising and submitting the ethics application.

Adding Project Members to a Project
To authorise access to the project for other PMs, you are required to:

- nominate members and designate their appropriate position in the project (e.g. Delegate, Principal Investigator (PI), Associate Investigator (AI), RGM or Sponsor). The positions will align with security access in the project. If you are unsure refer to User Roles in the RGS Help Wiki https://rgsuat.health.wa.gov.au/rgs-help/pages/help-Wiki-apps
- allocate sites to PIs and their delegates for the project; and
- send an invitation.

You are able to designate one person to be your CPI Delegate who will then have all the permissions you have, with the exception of authorising the ethics application.

Adding PMs to a Project who are not Research Users in the RGS
A person can only be added as a PM if they are currently a RGS Research User. You will need to contact any member of your project who is not registered with the RGS (using the provided template) to request that they complete the New User Sign Up form.

Should you require assistance with using the RGS, please contact the RGS Administrator.
### Active Projects

<table>
<thead>
<tr>
<th>PRN</th>
<th>Project Title</th>
<th>My Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>RGS0000000003</td>
<td>A pilot investigation into the early adjunctive use of virtual game therapy and the effects on patient motivation, pain management, coping behaviour and mobility of patients with burns</td>
<td>CPI, PI</td>
</tr>
<tr>
<td>RGS0000000004</td>
<td>Does education into warning signs of heart attack reduce emergency presentations in people who have previously suffered a suspected attack.</td>
<td>CPI, PI</td>
</tr>
<tr>
<td>RGS0000000009</td>
<td>Evaluation of an early multidisciplinary group intervention to improve communicative ability and psychosocial adjustment following traumatic brain injury</td>
<td>CPI, PI</td>
</tr>
<tr>
<td>RGS0000000054</td>
<td>A Randomized, Multicenter, Open-Label, Phase 3 Study of Acalabrutinib (ACP-196) Versus Investigator’s Choice of Either Idelalisib Plus Rituximab or Bendamustine Plus Rituximab in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia</td>
<td>CPI, PI</td>
</tr>
</tbody>
</table>

### Closed Projects

### Archived Projects
PROJECT | Does education into warning signs of heart attack reduce emergency presentations in people who have previously suffered a suspected attack.

Feasibility Assessment | Document Preparation | Submission and Review | Approval and Authorisation | Monitoring | Archived

PRN: RG500000000004
Project type: Research
Protocol number: HEART5E
External HREC ref: None

Project status: Active
Short title:
Acronym: CPI: Henry Amberley
Lead HREC: Sir Charles Gairdner Osborne Park Health Care Group Human Research Ethics Committee (EC00271)

My Role(s): CPI, PI

Sites | Members | Project Details | Forms & Documents | Declarations

Comments | Letters | Publications | Summary | Timeline

Reports | History
Jurisdiction where the project will be conducted within Australia:

- Inter-jurisdictional (across Australia)

<table>
<thead>
<tr>
<th>Site Name</th>
<th>Organisation Type</th>
<th>Jurisdiction</th>
<th>Region</th>
<th>Status</th>
<th>Select</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fiona Stanley Hospital</td>
<td>Public</td>
<td>WA</td>
<td>South Metropolitan Health Service</td>
<td>Active</td>
<td></td>
</tr>
<tr>
<td>Perth Children's Hospital</td>
<td>Public</td>
<td>WA</td>
<td>Child and Adolescent Health Service</td>
<td>Active</td>
<td></td>
</tr>
<tr>
<td>Sir Charles Gairdner Hospital</td>
<td>Public</td>
<td>WA</td>
<td>North Metropolitan Health Service</td>
<td>Active</td>
<td></td>
</tr>
</tbody>
</table>

Add Project Site(s) | Remove | Activate/Deactivate Site

Can't find site? [Request for a new site]
## Members

<table>
<thead>
<tr>
<th>Name</th>
<th>P.H.O.</th>
<th>Position</th>
<th>Current Organisation</th>
<th>Project Site</th>
<th>Date Added</th>
<th>Status Change Date</th>
<th>Select</th>
</tr>
</thead>
<tbody>
<tr>
<td>Henry Amberley</td>
<td>WA</td>
<td>CPI</td>
<td>Sir Charles Gairdner Hospital</td>
<td>All</td>
<td>4/10/2016</td>
<td>4/10/2016</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>PI</td>
<td>Sir Charles Gairdner Hospital</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jane Mitchell</td>
<td>WA</td>
<td>PI</td>
<td>Royal Perth Hospital</td>
<td>Fiona Stanley Hospital</td>
<td>4/10/2016</td>
<td>4/10/2016</td>
<td></td>
</tr>
<tr>
<td>Alison French</td>
<td>WA</td>
<td>PI Delegate</td>
<td>Sir Charles Gairdner Hospital</td>
<td>Sir Charles Gairdner Hospital</td>
<td>4/10/2016</td>
<td>4/10/2016</td>
<td></td>
</tr>
</tbody>
</table>

### Inactive

<table>
<thead>
<tr>
<th>Name</th>
<th>P.H.O.</th>
<th>Position</th>
<th>Current Organisation</th>
<th>Project Site</th>
<th>Date Added</th>
<th>Status Change Date</th>
</tr>
</thead>
</table>

### CPI Change Pending

<table>
<thead>
<tr>
<th>Name</th>
<th>P.H.O.</th>
<th>Position</th>
<th>Current Organisation</th>
<th>Status</th>
<th>Date Added</th>
</tr>
</thead>
</table>

### Invited

<table>
<thead>
<tr>
<th>Name</th>
<th>P.H.O.</th>
<th>Position</th>
<th>Current Organisation</th>
<th>Project Site</th>
<th>Date Added</th>
<th>Status Change Date</th>
</tr>
</thead>
</table>

### Declined

<table>
<thead>
<tr>
<th>Name</th>
<th>P.H.O.</th>
<th>Position</th>
<th>Current Organisation</th>
<th>Status</th>
<th>Date Added</th>
<th>Status Change Date</th>
</tr>
</thead>
</table>
Project name: House hold robotics: autonomous devices for lawn mowing and vacuuming to reduce musculoskeletal lower back injuries

PRN: RG00000000002
Project type: Research
Short title: House hold robotics to reduce lower back injuries
Protocol number:
Acronym:
Lead HREC approval status: Pending
Lead HREC:

1. Project

Protocol version number: 1
Protocol version date: 03/09/2016

Broad research area: Health services research

NHMRC

NHMRC group: HUMAN MOVEMENT AND SPORTS SCIENCE

NHMRC fields of research:
- Exercise Physiology
- Human Movement and Sports Science not elsewhere classified

Research Area Conditions

Broad health condition: Musculoskeletal
Specific condition: Other muscular and skeletal disorders

Research focus: Prevention

Keywords: injury; injuries; spinal; spine; musculoskeletal; device; back; lower

Project summary:
Using robotic assistance to prevent or mitigate back pain. An exoskeleton body is designed to be suspended from the ceiling to help lift heavy items and take care of the balance of the skeleton. This project proposes the...
2. Sites

Number of sites - WA Health sites:*  
2

Number of sites - Non-WA Health sites within Australia:*  
0

Number of sites - Non-WA sites within Australia:*  
0

Site names within Australia:*  
Please select...

3. Scientific and Ethical Review

Jurisdictions where project will be conducted within Australia:*  
Within WA Health only

Single or multi-centre distribution:*  
Multi-centre

Sites under Approval - name of the site(s) which will rely on the ethical approval from the nominated HREC(s):*  
Fiona Stanley Hospital, Fremantle Hospital

Type of ethical review:*  
WA Health single ethical review

Risk type:*  
Low risk

4. Disclosure of Interest

Have any of the investigators involved with the project have a conflict of interest to declare?*  
No

5. Project Duration

Expected start date:*  
03/10/2016

Expected finish date:*  
31/10/2017

Expected date of first participant recruitment:*  
03/10/2016

Duration:*  

6. Participants

6.1 Source and Number

Involves healthy volunteers:*  
No
### 6. Participants

#### 6.1 Source and Number

<table>
<thead>
<tr>
<th>Question</th>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>Involves healthy volunteers:</td>
<td>Yes</td>
</tr>
<tr>
<td>Participant age group:</td>
<td>26-65 years</td>
</tr>
<tr>
<td>Participant gender:</td>
<td>All</td>
</tr>
<tr>
<td>What is the expected total number of participants at all Australian sites</td>
<td>25</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>People whose primary language is other than English (LOTE):</td>
<td>Probable coincidental recruitment</td>
</tr>
<tr>
<td>Women who are pregnant and the human fetus:</td>
<td>Design specifically excludes</td>
</tr>
<tr>
<td>Children and/or young people (&lt;18 years):</td>
<td>Design specifically excludes</td>
</tr>
<tr>
<td>People in existing dependent or unequal relationships:</td>
<td>Probable coincidental recruitment</td>
</tr>
<tr>
<td>People highly dependent on medical care who may be unable to give consent:</td>
<td>Design specifically excludes</td>
</tr>
<tr>
<td>People with cognitive impairment, an intellectual disability or a mental illness:</td>
<td>Design specifically excludes</td>
</tr>
<tr>
<td>Aboriginal people:</td>
<td>Probable coincidental recruitment</td>
</tr>
<tr>
<td>People who may be involved in illegal activity:</td>
<td>Design specifically excludes</td>
</tr>
<tr>
<td>People in other countries:</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Section</td>
<td>Details</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>1. Credential and Training</td>
<td>Is there any relevant certification, accreditation or credentialing requirements relevant to the conduct of this research? No</td>
</tr>
<tr>
<td>2. Methodology</td>
<td>Indicate if the project involves any of the following project specific requirements: Not applicable</td>
</tr>
<tr>
<td>3. Indemnity and Insurance</td>
<td></td>
</tr>
<tr>
<td>3.4 Non-clinical trial research project</td>
<td>Does the research project (that is not a clinical trial) involve an external entity? No</td>
</tr>
<tr>
<td>4. Research Agreement</td>
<td>Is a research agreement with an external organisation required? No</td>
</tr>
<tr>
<td>5. Intellectual Property</td>
<td>Is there a possibility of significant new Intellectual Property being developed from the project? No</td>
</tr>
<tr>
<td>6. Resource and budget Information</td>
<td>Will participants receive any payment or expenses for participation in the research? No</td>
</tr>
<tr>
<td></td>
<td>Is there an external funding organisation? No</td>
</tr>
</tbody>
</table>
Evaluation of an early multidisciplinary group intervention to improve hospital stay in stroke patients

Project type: Research

Protocol number: 123-589

Lead HREC: Sir Charles Gairdner Group Human Research Ethics Committee (EC00271)

PRN: RGS00000001006

Project status: Active

Ethics approval status: Pending

Short title:

Acronym:

CPI: Albert Macintosh

External HREC ref: None

Internal & External HREC

Will the project be reviewed by a Lead HREC outside of WA Health (i.e. external Lead HREC)?

No

Lead HREC (& code):

Sir Charles Gairdner Group Human Research Ethics Committee (EC00271)

Additional HREC (Specialist):
### Tasks

#### New Group Tasks
There are no items to show in this view.

#### Taken Group Tasks
There are no items to show in this view.

#### Declined Group Tasks
There are no items to show in this view.

#### My Tasks

<table>
<thead>
<tr>
<th>Task Name</th>
<th>Task Outcome</th>
<th>Initiator</th>
<th>Created</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project General Task</td>
<td>Pending</td>
<td>Albert Macintosh</td>
<td>14/07/2016</td>
<td>28/07/2016</td>
</tr>
</tbody>
</table>

#### Task Type: Project General Task (1)

#### Tasks Assigned to Others
There are no items to show in this view.
User profile for Albert Macintosh

Mr Albert Macintosh

Professor
Curtin University
Curtin University
School of Medicine, Kent Street
Bentley
Western Australia
Australia
08 9222 6413

Area of Research Speciality: Cardiovascular | Coronary heart disease
Primary Email:

Assignee comments:

Task status: Pending
Finish Task Decline Task Cancel
An observational pilot study of 16 weeks of anti-inflammatory doses of fish oils in patients with symptomatic osteoarthritis of the hands

PRN: RGS0000000001
Project type: Research
Protocol number: 123- abc
External HREC ref: None

Select Ethics Approval Forms

- WA Health Ethics Application Form (WAHEAF)
- WA-Specific Module (WASM)
PROJECT | An observational pilot study of 16 weeks of anti-inflammatory doses of fish oils in patients with symptomatic osteoarthritis of the hands

<table>
<thead>
<tr>
<th>PRN: RGS00000000001</th>
<th>Project status: Active</th>
<th>Ethics approval status: Pending</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project type: Research</td>
<td>Short title:</td>
<td>CPI: Diana Forster</td>
</tr>
<tr>
<td>Protocol number: 123- abc</td>
<td>Acronym:</td>
<td>Lead HREC: Sir Charles Gairdner Group Human Research Ethics Committee (EC00271)</td>
</tr>
<tr>
<td>External HREC ref: None</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Forms & Documents

<table>
<thead>
<tr>
<th>Form Name</th>
<th>Version</th>
<th>Status</th>
<th>Locked By</th>
<th>Updated By</th>
<th>Select</th>
</tr>
</thead>
<tbody>
<tr>
<td>WA Health Ethics Application Form (WAHEAF)</td>
<td>1.0</td>
<td>Pending</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Find information on Research Authorisation and Monitoring Forms

Find information on Research Authorisation and Monitoring Forms

**Application**

**Ethics Approval**

**Active**
WA Health Ethics Application Form

1. Introduction

1.1 Project

1.1.0 PRN: RGS0000000001

1.1.1 Project title: An observational pilot study of 16 weeks of anti-inflammatory doses of fish oils in patients with symptomatic osteoarthritis of the hands

1.1.2 Short title:

1.1.3 Acronym:

1.1.4.1 Protocol number: 123-abc

1.1.4.2 Protocol version number: 1

1.1.4.3 Protocol version date: 15/02/2016

1.1.5 Project summary: To see if taking fish oil reduces the inflammation in people with osteoarthritis in their hands

1.2 Sites

1.2.1 Number of sites - Australia: 1

1.2.2 Number of sites - Non-Australian sites: 0

1.2.3 Site names within Australia: Sir Charles Gairdner Hospital, Fiona Stanley Hospital

1.3 Scientific and Ethical Review

1.3.1 Reviewing HREC: Sir Charles Gairdner Group Human Research Ethics Committee
1.3 Scientific and Ethical Review

1.3.1 Reviewing HREC: Sir Charles Gairdner Osborne Park Health Care Group HREC

1.3.2 Single or multi-centre distribution: 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):
Fiona Stanley Hospital, Sir Charles Gairdner Hospital

1.3.4 Risk type: Low risk

1.3.5 Is this project being submitted to (or has it been previously submitted to) another Australian HREC? No

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:
Reviewed by the UWA school of medicine peer review council

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:
Consumer group of previous burns patients reviewed the information sheets

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:

<table>
<thead>
<tr>
<th>Funder Organisation Type</th>
<th>Funder Organisation Name</th>
<th>Estimate $ amount of any funding (for all sites)</th>
<th>Estimate $ amount of any in-kind-support (for all sites)</th>
<th>Funding is confirmed / received or being sought</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not for Profit</td>
<td>Raine Foundation</td>
<td>$50,000.00</td>
<td>$0.00</td>
<td>Confirmed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sub total</td>
<td></td>
<td>$50,000.00</td>
</tr>
</tbody>
</table>

Total funding/in-kind support for all sites: $50,000.00

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

1.6.3 Is this a project where capitation payments are to be made? No
2. Project Team

2.1 Investigators

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Qualifications and Expertise relevant to the project</th>
<th>GCP Certified</th>
<th>Student</th>
<th>Name and location of student supervisor</th>
<th>Site(s) for which the investigator is responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPI</td>
<td>Dr Henry Amberley</td>
<td>Has done a heap of research</td>
<td>Yes</td>
<td>No</td>
<td>All</td>
<td></td>
</tr>
<tr>
<td>PI</td>
<td>Sir Charles Gairdner Hospital</td>
<td>Medical Emergency Department Doctor</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><a href="mailto:diana4ster+16@gmail.com">diana4ster+16@gmail.com</a></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2.2 Disclosure of Interest

2.2.1 Have any of the investigators involved with the project have a conflict of interest to declare? No

2.3 Contact person for project

2.3.1 Contact person for this project:

Name: Dr Henry Amberley
Address: Ground Floor G Block Hospital Avenue Nedlands Western Australia Australia 6009
Organisation: Sir Charles Gairdner Hospital
Department: Medical | Emergency Department
Position: Doctor
Phone (Business): 9222 6413
Mobile: 0411 034 215
Email: diana4ster+16@gmail.com
4.1.3 What is the expected number of participants for each WA Health site involved with the project?

<table>
<thead>
<tr>
<th>Site</th>
<th>Number of Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fiona Stanley Hospital</td>
<td>30</td>
</tr>
<tr>
<td>Sir Charles Gairdner Hospital</td>
<td>30</td>
</tr>
</tbody>
</table>

4.2 What categories of people will participate in research?

4.2.1 People whose primary language is other than English (LOTE): Design specifically excludes
4.2.2 Women who are pregnant and the human fetus: Not applicable
4.2.3 Children and/or young people (i.e. <18 years): Not applicable
4.2.4 People in existing dependent or unequal relationships: Design specifically excludes
4.2.5 People highly dependent on medical care who may be unable to give consent: Design specifically excludes
4.2.6 People with a cognitive impairment, an intellectual disability or a mental illness: Design specifically excludes
4.2.7 Aboriginal people: Probable coincidental recruitment
4.2.8 People who may be involved in illegal activity: Design specifically excludes
4.2.9 People in other countries: Design specifically excludes

4.3 Recruitment

4.3.1 Process used to identify potential participants for the project at the site(s): Participants will be identified through the burns units

4.3.2 How initial contact will be made with potential participants at the site(s): A researcher will approach in patients in the hospital to assess whether they are interested in being involved.

4.3.3 Will recruitment be from small rural communities? No

4.6 Aboriginal people

4.6.1 Does the project involve Aboriginal people in the categories that require WAAHEC approval? No

4.9 Consent

4.9.1 Will the research involve informed consent of participants? Yes
4.9.2 How will informed consent be obtained/recorded?
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.

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wyatt Darcy</td>
<td>CPI</td>
<td>(Automatically signed when form is Authorised)</td>
<td></td>
</tr>
</tbody>
</table>

Unlock   Authorise

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Henry Amberley</td>
<td>CPI, PI</td>
<td>Signed</td>
<td>28/09/2016</td>
</tr>
</tbody>
</table>
### Forms

#### Site / Organisation

<table>
<thead>
<tr>
<th>Form Name</th>
<th>Version</th>
<th>Status</th>
<th>Locked By</th>
<th>Updated By</th>
<th>Select</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site Specific Assessment (SSA) Form</td>
<td>1.0</td>
<td>In Progress</td>
<td>Diana Forster</td>
<td>Diana Forster</td>
<td></td>
</tr>
<tr>
<td>Budget Form</td>
<td>1.0</td>
<td>In Progress</td>
<td>Diana Forster</td>
<td>Diana Forster</td>
<td></td>
</tr>
</tbody>
</table>
PRN: RGS00000000028

Project title: Does cheese consumption make fat people even fatter?

Select Site Authorisation Forms

<table>
<thead>
<tr>
<th>Form Name</th>
<th>Select</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access Request (AR) Form</td>
<td></td>
</tr>
<tr>
<td>Site Specific Assessment (SSA) Form</td>
<td>✔</td>
</tr>
</tbody>
</table>

SSA form and budget form for which site(s): Bentley Health Service

Add Selected Forms to Project  Close
Site Specific Assessment (SSA) Form

Fiona Stanley Hospital

1. Project Details

1.1 Project

1.1.0 PRN: RGS0000000003

1.1.1 Project title: A pilot investigation into the early adjunctive use of virtual games on effects on patient motivation, pain management, coping behaviour of patients with burns

1.1.2 Short title: game therapy pain management

1.1.3 Acronym:

1.1.4 Protocol number: GT123

1.1.5 Protocol version number: 1

1.1.6 Protocol version date: 31/08/2016

1.1.7 Coordinating Principal Investigator: Henry Amberly

1.2 Scientific and Ethical Review

1.2.1 Reviewing HREC: Sir Charles Gairdner Osborne Park Health Care Group HREC (EC00271)

Submit the HREC approval letter with your application

1.2.2 Single or multi-centre distribution: Multi-centre

1.2.3 Jurisdictions where project will be conducted within Australia: Within WA Health only

1.2.4 Type of ethical review: WA Health single ethical review

1.2.5 Risk type: 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

### 1.3.2 Number of sites involved with the project

<table>
<thead>
<tr>
<th>Type of Site</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>WA Health sites:</td>
<td>2</td>
</tr>
<tr>
<td>Non-WA Health sites within WA:</td>
<td>0</td>
</tr>
<tr>
<td>Non-WA sites within Australia:</td>
<td>0</td>
</tr>
<tr>
<td>Non-Australian sites:</td>
<td>0</td>
</tr>
</tbody>
</table>

### 1.4 Project Summary

1.4.1 Project Summary: To assess whether playing computer games lowers pain perception

### 1.5 Anticipated Start and Finish Dates for the Research Project at the Site(s)

<table>
<thead>
<tr>
<th>Date Type</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start Date:</td>
<td>03/10/2016</td>
</tr>
<tr>
<td>Finish Date:</td>
<td>31/10/2019</td>
</tr>
<tr>
<td>Duration:</td>
<td>3 year(s)</td>
</tr>
</tbody>
</table>
Form is locked out by you for editing.

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 interventional research other than clinical trials

2.2 NHMRC Group and Fields of Research

2.2.1 NHMRC group:
COMPLEMENTARY/ALTERNATIVE MEDICINE

2.2.2 NHMRC fields of research:
Complementary and Alternative Medicine not elsewhere classified

<< Previous  Next >>  Save  Save and Close  Cancel
3. Investigators - Fiona Stanley Hospital

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Qualifications and Expertise relevant to the project</th>
<th>GCP Certified</th>
<th>Student?</th>
<th>Name and location of student Supervisor</th>
<th>Site(s) for which the investigator is responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI</td>
<td>Dr Henry Amberley</td>
<td>Has done a heap of research</td>
<td>Yes</td>
<td>No</td>
<td>Fiona Stanley Hospital, Sir Charles Gairdner Hospital</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sir Charles Gairdner</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.3 Conflict of Interest

3.3.1 Have any of the investigators involved with the project have a conflict of interest to declare? **No**

3.4 Site Contact Person

Henry Amberley (Coordinating Principal Investigator, Principal Investigator)
4.Credentialing and Training

4.1 Is there any relevant certification, accreditation or credentialing requirements relevant to the conduct of this research?  
No

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

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?  
No
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?

<table>
<thead>
<tr>
<th>Site</th>
<th>Number of Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fiona Stanley Hospital</td>
<td></td>
</tr>
</tbody>
</table>

5.1.2 Where will the participant’s project visits/follow-up occur (venue)?

5.2 What categories of people will participate in research?

5.2.1 People whose primary language is other than English (LOTE): Design specifically excludes

5.2.2 Women who are pregnant and the human fetus: Not applicable

5.2.3 Children and/or young people (i.e. < 18 years): Not applicable

5.2.4 People in existing dependent or unequal relationships: Design specifically excludes

5.2.5 People highly dependent on medical care: Design specifically excludes

5.2.6 People with a cognitive impairment, an intellectual disability or a mental illness: Design specifically excludes

5.2.7 Aboriginal people: Probable coincidental recruitment

5.2.8 People who may be involved in illegal activity: Design specifically excludes

5.2.9 People in other countries: Design specifically excludes

5.3 Recruitment Process

5.3.1 Process used to identify potential participants for the project at the site(s):
Participants will be identified through the burns units

5.3.2 How initial contact will be made with potential participants at the site(s):
A researcher will approach patients in the hospital to assess whether they are interested in being involved.
17. Funds Management Details

17.1 Is there an external funding organisation? Yes

<table>
<thead>
<tr>
<th>Funder Organisation Name</th>
<th>Funder Organisation Type</th>
<th>ABN</th>
<th>Profile</th>
<th>Major Funder?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Health</td>
<td>Government - State (WA)</td>
<td></td>
<td>View</td>
<td>No</td>
</tr>
<tr>
<td>Sir Charles Gairdner Hospital</td>
<td>Government - State (WA)</td>
<td></td>
<td>View</td>
<td>No</td>
</tr>
<tr>
<td>Self Funded</td>
<td>Other</td>
<td></td>
<td>View</td>
<td>No</td>
</tr>
</tbody>
</table>

17.1.2 External Funder Organisation Contact Details

Name: Ms Jodie Hegarty
Address: 189 Royal Street East Perth Western Australia Australia 6004
Organisation: Department of Health
Department: Office of the Chief Medical Officer
Position: Senior Policy Officer
Phone (Business): 9222 2069
Email: Jodie.Hegarty@health.wa.gov.au

17.2 WA Health Account Details

17.2.1 WA Health Cost Centre and Account Details: 

<< Previous    Next >>    Save    Save and Close    Mark Complete    Cancel
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/355/95).
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.

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Henry Amberley</td>
<td>PI</td>
<td>Signed</td>
<td>15/09/2016</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Status</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diana Forster</td>
<td>Head of Department - Sir Charles Gairdner Hospital</td>
<td>Pending</td>
<td>Signed</td>
<td>15/09/2016</td>
</tr>
</tbody>
</table>
## Site Project Funding / Support

<table>
<thead>
<tr>
<th>Available Funders</th>
<th>Funder Organisation Type</th>
<th>$ Amount of Funding by Sponsor or Funder</th>
<th>$ Amount of In-Kind Support</th>
<th>Funding Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Health</td>
<td>Government - State (WA)</td>
<td>$32,860.00</td>
<td></td>
<td>Confirmed</td>
</tr>
<tr>
<td>Self Funded</td>
<td>Other</td>
<td></td>
<td>$1,950.00</td>
<td>Confirmed</td>
</tr>
<tr>
<td>Sir Charles Gairdner Hospital</td>
<td>Government - State (WA)</td>
<td>$4,000.00</td>
<td>$7,000.00</td>
<td>Confirmed</td>
</tr>
</tbody>
</table>

If you cannot find a funder, please update the ‘Funder Contact Information’ found in the Governance Information section of the Project Details tab.

### Sir Charles Gairdner Hospital

**Proposed Number of Participants for this site:** 30  
**Expected project timeframe for this site:** 2 year(s)

*Participant also includes a person’s data, information or biological sample.*

### Research Department

**Pain Management**

<table>
<thead>
<tr>
<th>$2000.00</th>
<th>Department of Health</th>
<th>$0.00</th>
<th>Grant</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Major Category</th>
<th>Service/Support Item Provided</th>
<th>Cost Description</th>
<th>Cost Per Item</th>
<th>Quantity</th>
<th>Total Cost</th>
<th>Cost Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethics Approval</td>
<td>Preparation of the HREC application</td>
<td>RN to prepare</td>
<td>$2000.00</td>
<td>1</td>
<td>$2000.00</td>
<td>Shared</td>
</tr>
</tbody>
</table>
Resource and Budget
Research Education & Training

The RETP aims to provide busy health practitioners with open access to comprehensive research skills training across the entire research process.

The Program provides:

- online training modules across the whole research process
- Access to additional research skills resources
- Links to other training opportunities in research skills, including the PMH Research Skills Seminar Series.

Department of Health Budget Workshops

The Department of Health’s Research Development Unit has been conducting a series of presentations across WA Health to provide strategies for developing research budgets and completing the budget spreadsheet in the current site specific assessment form, as well as an introduction to the future templates.

- Research Budgets - Costs and Funding presentation (PDF 2.0MB)
- Research Budgets - Costs and Funding handout (PDF 1.4MB)

Clinical Trials and Research Governance Modules

Australian Clinical Trials

The Australian Clinical Trials website hosts 4 modules which provide an introduction to the clinical trials environment, clinical research ethics and ethical review and research governance processes.

Access the eLearning modules (external site).
## Site Authorisation

### Active

#### Forms

<table>
<thead>
<tr>
<th>Site / Organisation</th>
<th>Form Name</th>
<th>Version</th>
<th>Status</th>
<th>Locked By</th>
<th>Updated By</th>
<th>Select</th>
</tr>
</thead>
<tbody>
<tr>
<td>Graylands Hospital</td>
<td>Site Specific Assessment (SSA) Form</td>
<td>1.0</td>
<td>Completed</td>
<td></td>
<td>Sarah Howell</td>
<td>False</td>
</tr>
<tr>
<td></td>
<td>Budget Form</td>
<td>1.0</td>
<td>In progress</td>
<td></td>
<td>Sarah Howell</td>
<td>False</td>
</tr>
<tr>
<td></td>
<td>Access Request (AR) Form</td>
<td>1.0</td>
<td>Authorised</td>
<td></td>
<td>Nola Mammat</td>
<td>False</td>
</tr>
</tbody>
</table>
Resource and Budget Information

Department(s) Selection

- Department of Health
  - Proposed Number of Participants for this site: 25
  - Expected project timeframe for this site: 3 year(s)

*Participant also includes a person’s data, information or biological sample.

<table>
<thead>
<tr>
<th>Department Name</th>
<th>Type</th>
<th>Head Of Department</th>
<th>Authorisation Status</th>
<th>Select</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office of the Chief Medical Officer</td>
<td>Research Department</td>
<td>Tanya Harley</td>
<td>Pending</td>
<td></td>
</tr>
</tbody>
</table>

Click **Invite to Quote** to create Task and send email notification to Department(s) added with ‘Pending’ status.

Invite to Quote

Buttons: Next >>, Save, Save and Close, Cancel
## Department(s) Selection

- Fiona Stanley Hospital

**Proposed Number of Participants for this site:** 5

**Expected project timeframe for this site:** 4 year(s)

*Participant also includes a person’s data, information or biological sample.*

<table>
<thead>
<tr>
<th>Department Name</th>
<th>Type</th>
<th>Head Of Department</th>
<th>Authorisation Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastroenterology</td>
<td>Research Department</td>
<td>Katherine Coltrona</td>
<td>Invited</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>Supporting Department</td>
<td>Katherine Coltrona</td>
<td>Invited</td>
</tr>
<tr>
<td>PathWest</td>
<td>Supporting Department</td>
<td>Katherine Coltrona</td>
<td>Invited</td>
</tr>
<tr>
<td>State Rehabilitation Services</td>
<td>Supporting Department</td>
<td>Katherine Coltrona</td>
<td>Invited</td>
</tr>
<tr>
<td>Medical Imaging</td>
<td>Supporting Department</td>
<td>Katherine Coltrona</td>
<td>Invited</td>
</tr>
<tr>
<td>Task Name</td>
<td>Task Outcome</td>
<td>Initiator</td>
<td>Created</td>
</tr>
<tr>
<td>-----------</td>
<td>--------------</td>
<td>-------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Invitation to Provide Quote and Authorise/Decline in Budget Spreadsheet</td>
<td>Pending</td>
<td>Katherine Coltrona</td>
<td>1/11/2016</td>
</tr>
<tr>
<td>Invitation to Provide Quote and Authorise/Decline in Budget Spreadsheet</td>
<td>Pending</td>
<td>Katherine Coltrona</td>
<td>1/11/2016</td>
</tr>
<tr>
<td>Invitation to Provide Quote and Authorise/Decline in Budget Spreadsheet</td>
<td>Pending</td>
<td>Katherine Coltrona</td>
<td>1/11/2016</td>
</tr>
<tr>
<td>Invitation to Provide Quote and Authorise/Decline in Budget Spreadsheet</td>
<td>Pending</td>
<td>Katherine Coltrona</td>
<td>1/11/2016</td>
</tr>
</tbody>
</table>

**Task Form**

- Group task?: No
- Task type: Invitation to Provide Quote and Authorise/Decline in Budget Spreadsheet
- PRN: RGS0000000000
  - Can metformin be used safely in dialysis patients?
- Start date: 1/11/2016
- Due date: 8/11/2016
- Assignee: Katherine Coltrona
- Initiator comments: Can metformin be used safely in dialysis patients?
- PRN: RGS0000000000
- Project Title: Can metformin be used safely in dialysis patients?
<table>
<thead>
<tr>
<th>Major Category</th>
<th>Service &amp; Support Item Provided</th>
<th>Cost Description</th>
<th>Cost per Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial initiation</td>
<td>Departmental set up</td>
<td>Set up fee</td>
<td>$</td>
</tr>
<tr>
<td>Site closeout visit</td>
<td>Site closeout visit</td>
<td>Close out fee</td>
<td>$</td>
</tr>
<tr>
<td>Pharmacy/Investigation</td>
<td>Stock management – drug stoc</td>
<td>Annual Administration fee</td>
<td>$</td>
</tr>
<tr>
<td>Pharmacy/Investigation</td>
<td>Stock management – expiry mi</td>
<td>Annual storage fee</td>
<td>$</td>
</tr>
<tr>
<td>Pharmacy/Investigation</td>
<td>Drug preparation and dispensi</td>
<td>Dispensing Fee</td>
<td>$</td>
</tr>
<tr>
<td>Pharmacy/Investigation</td>
<td>Drug preparation and dispensi</td>
<td>Remote monitoring fee - $100 per instance</td>
<td>$</td>
</tr>
</tbody>
</table>

Please select...
## Site Project Budget

- **Total Actual Costs:** $9,875.00
- **Total Authorised Costs:** $1,000.00
- **Total Funding:** $9,875.00
- **Shortfall (or Surplus):** $8,875.00

**Project specific cost:** $8,875.00

**Shared cost:** $0.00

### Royal Perth Hospital

- **Proposed number of participants in this site:** 50
- **Expected project timeframe for this site:** 2 year(s)

*Participant also includes a person's data, information or biological sample.*

### Research Department

### Emergency Department

<table>
<thead>
<tr>
<th>Major Category</th>
<th>Service &amp; Support Item Provided</th>
<th>Cost Description</th>
<th>Cost per Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical services</td>
<td>Overhead Charge - percentage</td>
<td></td>
<td>25.00%</td>
</tr>
<tr>
<td>Ethics approval</td>
<td>Ethics review</td>
<td></td>
<td>$3,500.00</td>
</tr>
<tr>
<td>Site specific assessment</td>
<td>Site processing and review</td>
<td></td>
<td>$3,500.00</td>
</tr>
<tr>
<td>Clinical services</td>
<td>Nursing services</td>
<td>consent</td>
<td>$100.00</td>
</tr>
</tbody>
</table>

### Third Party Agency

#### SKG Radiology

- **Authorised - Mark Woodman** 20/10/2016

<table>
<thead>
<tr>
<th>Major Category</th>
<th>Service &amp; Support Item Provided</th>
<th>Cost Description</th>
<th>Cost per Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical services</td>
<td>Radiation therapy planning and treatment</td>
<td>CT</td>
<td>$100.00</td>
</tr>
</tbody>
</table>

### General Comments (mandatory in cases of shortfall)
### Forms

<table>
<thead>
<tr>
<th>Form Name</th>
<th>Version</th>
<th>Status</th>
<th>Locked By</th>
<th>Updated By</th>
<th>Select</th>
</tr>
</thead>
<tbody>
<tr>
<td>Master PICF - Main</td>
<td>1.0</td>
<td>Attached</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Master PICF - Genetics</td>
<td>0.0</td>
<td>Not Attached</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Documents

- Find recommended Document Templates [here](#).

<table>
<thead>
<tr>
<th>Doc ID</th>
<th>Document Name</th>
<th>Version</th>
<th>Status</th>
<th>Attached By</th>
<th>Date Attached</th>
<th>Select</th>
</tr>
</thead>
<tbody>
<tr>
<td>1006</td>
<td>Master PICF - Main</td>
<td>1.0</td>
<td>Attached</td>
<td>Albert Macintosh</td>
<td>04/07/2016</td>
<td></td>
</tr>
<tr>
<td>1007</td>
<td>Master PICF - Genetics</td>
<td>0.0</td>
<td>Not Attached</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Submitted

- Site Authorisation

### Active

- Add
- Remove
- Authorise
- Unauthorise
- Print

- Submit to Ethics
Add Project Documents

PRN: RGS0000001011

Project Title: Input of a Multidisciplinary Device to Accompany the Announce of Diagnosis for Young Children With Serious Constitutional Hemorrhagic Disease and Their Families

Document

Document Type: Please select...

Document Name: Human Research Ethics Application (HREA)

Status:

Document Details

Version Number: 

Is this a hard copy (p): 

Save
Project Title: Input of a Multidisciplinary Device to Accompany the Announce of Diagnosis for Young Children With Serious Constitutional Hemorrhagic Disease and Their Families

Document Type: Human Research Ethics Application (HREA)
Document Name: Sample HREA
Status: Not Attached

Version Number: 1
Version Date: 24/07/2016

Is this a hard copy (paper) or soft copy (electronic) document? Soft Copy (Electronic)

Select File: Sample HREA v1.0.docx
Allowed Types: PDF, DOC, DOCX,
<table>
<thead>
<tr>
<th>Form Name</th>
<th>Version</th>
<th>Status</th>
<th>Locked By</th>
<th>Updated By</th>
<th>Select</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site Specific Assessment (SSA) Form</td>
<td>1.0</td>
<td>Completed</td>
<td></td>
<td>Sarah Howell</td>
<td></td>
</tr>
<tr>
<td>Budget Form</td>
<td>1.0</td>
<td>In progress</td>
<td></td>
<td>Sarah Howell</td>
<td></td>
</tr>
<tr>
<td>Access Request (AR) Form</td>
<td>1.0</td>
<td>Authorised</td>
<td></td>
<td>Nola Mammatt</td>
<td></td>
</tr>
</tbody>
</table>
Submit an Application
<table>
<thead>
<tr>
<th>Doc ID</th>
<th>Document Name</th>
<th>Version</th>
<th>Status</th>
<th>Attached By</th>
<th>Date Attached</th>
<th>Select</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Participant information and consent form version 1</td>
<td>1.00</td>
<td>Attached</td>
<td>Wyatt Darcy</td>
<td>04/10/2016</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Protocol version 1</td>
<td>1.00</td>
<td>Attached</td>
<td>Wyatt Darcy</td>
<td>05/10/2016</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Survey questions</td>
<td>1.00</td>
<td>Attached</td>
<td>Wyatt Darcy</td>
<td>05/10/2016</td>
<td></td>
</tr>
</tbody>
</table>

Submit Project To Ethics

- **Project**: RGSS00000000005
- **Project title**: Influence of physical activity, obesity and smoking on survival after a prostate cancer diagnosis
- **Jurisdiction**: Western Australia
- **HREC**: LL UAT Specialist HREC (EC99999) *

Select the Forms and Documents for Submission:

<table>
<thead>
<tr>
<th>Document Type</th>
<th>Document Name</th>
<th>Version</th>
<th>Status</th>
<th>Select</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant Information Sheet and Consent Form (Master)</td>
<td>Participant information and consent form version 1</td>
<td>1.00</td>
<td>Authorised</td>
<td></td>
</tr>
<tr>
<td>Protocol</td>
<td>Protocol version 1</td>
<td>1.00</td>
<td>Authorised</td>
<td></td>
</tr>
<tr>
<td>Research Tools (questionnaires, surveys)</td>
<td>Survey questions</td>
<td>1.00</td>
<td>Authorised</td>
<td></td>
</tr>
</tbody>
</table>

If you wish to add comments about this submission, please go to the Comments tab.
Thank you. Your ethics submission was successful.

### Application

#### Ethics Approval

- **Active**
- **Submitted**

#### Forms

<table>
<thead>
<tr>
<th>Form Name</th>
<th>Version</th>
<th>Status</th>
<th>Submission Date</th>
<th>Validation Date</th>
<th>Review Decision Date</th>
<th>Approval Decision Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>WA Health Ethics Application Form (WAHEAF)</td>
<td>1.0</td>
<td>Submitted</td>
<td>04/07/2016</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Print**

#### Documents

<table>
<thead>
<tr>
<th>Doc ID</th>
<th>Document Name</th>
<th>Version</th>
<th>Status</th>
<th>Submission Date</th>
<th>Validation Date</th>
<th>Review Decision Date</th>
<th>Approval Decision Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1006</td>
<td>Master PICF - Main</td>
<td>1.0</td>
<td>Submitted</td>
<td>04/07/2016</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1007</td>
<td>Master PICF - Genetics</td>
<td>1.0</td>
<td>Submitted</td>
<td>04/07/2016</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**View** **Print**
Application

- Ethics Approval
- Site Authorisation

Active

Forms

**Site / Organisation**

- Department of Health

<table>
<thead>
<tr>
<th>Form Name</th>
<th>Version</th>
<th>Status</th>
<th>Locked By</th>
<th>Updated By</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site Specific Assessment (SSA) Form</td>
<td>1.0</td>
<td>Completed</td>
<td>Tanya Harley</td>
<td>Tanya Harley</td>
</tr>
<tr>
<td>Budget Form</td>
<td>1.0</td>
<td>Authorised</td>
<td>Tanya Harley</td>
<td>Tanya Harley</td>
</tr>
</tbody>
</table>

[Add] [Remove] [Authorise] [Unauthorize] [Print]

Documents

Find recommended Document Templates [here].

**Form / Site(s)**

- Site Specific Assessment (SSA) Form (Department of Health)

<table>
<thead>
<tr>
<th>Doc ID</th>
<th>Document Name</th>
<th>Version</th>
<th>Status</th>
<th>Attached By</th>
<th>Date Attached</th>
<th>Select</th>
</tr>
</thead>
<tbody>
<tr>
<td>33</td>
<td>consent form</td>
<td>1.0</td>
<td>Attached</td>
<td>Tanya Harley</td>
<td>12/10/2016</td>
<td></td>
</tr>
</tbody>
</table>

[Add] [Edit] [Remove] [Authorise] [Unauthorise] [Print]

Submit to Governance
<table>
<thead>
<tr>
<th>Timeline</th>
<th>Summary</th>
<th>Project Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Members</td>
<td>Sites</td>
<td>Declarations</td>
</tr>
<tr>
<td><strong>Forms &amp; Documents</strong></td>
<td>Letters</td>
<td>Comments</td>
</tr>
<tr>
<td>Publications</td>
<td>Reports</td>
<td>History</td>
</tr>
</tbody>
</table>

Thank you. Your governance submission was successful.
Assistance & Support
Contacts

In this page...

- General Enquiries
- WA Health Ethics Offices
- Contacts for Specialist HRECs External to WA Health
- Contacts for all WA HRECs
- WA Health Research Governance Offices

General Enquiries

Policy Advice
Katherine Coltrona, Senior Policy Officer
Research Development Unit, Department of Health
P: 08 9222 4332
E: Katherine.Coltrona@health.wa.gov.au

Contractual Advice
Don Black, Principal Policy Adviser
Legal and Legislative Services, Department of Health
E: Don.Black@health.wa.gov.au

RGS Business Assistance
The RGS Administrator will assist with RGS content (e.g. adding department, division, site, region, insurer or funder fields to dropdown menus)
E: RGSAdmin@health.wa.gov.au

RGS Technical Assistance
WA Health employees: contact your Service Desk
Non WA Health employees: RGS.Support@health.wa.gov.au
Thank You