

# WA Health Research Authorisation and Monitoring Forms Guidelines in RGS



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## 1 Introduction

The Research Governance Service (RGS) information technology system has been developed to support the WA Health system research governance policy and procedures and allow WA Health system entities to participate in national initiatives, including the National Mutual Acceptance (NMA) process and National Aggregated Statistics for Clinical Trials.

It provides a collaborative workspace for investigators, project members, sponsors, sites, Research Governance Officers (RGOs) and Human Research Ethics Committees (HRECs) to govern and report on human research through the life cycle of the project, from initial application to publication.

The concept behind RGS is that the information is entered once to be accessed/used multiple times.

### Approval/Authorisation

The RGS's function is to facilitate the scientific and ethical approval and site authorisation processes for human research projects conducted within WA Health system entities including accessing WA Health participants, their tissue or data.

The RGS allows investigators (or their delegates), project members and sponsors to complete and submit forms and supporting documents via the RGS to the relevant WA Health:

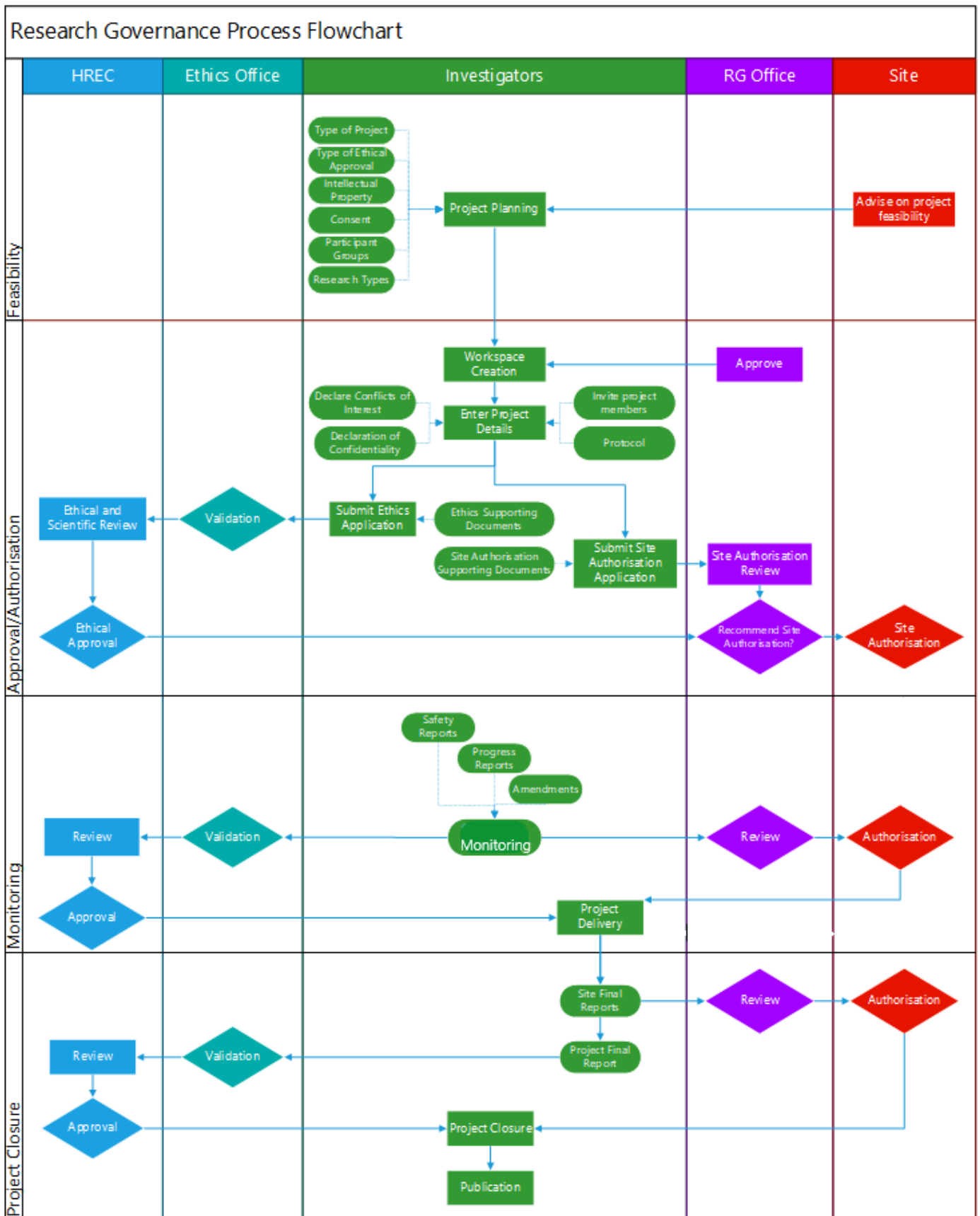
- HREC for scientific and ethical review and approval
- Research Governance (RG) Office for governance review and site authorisation.

Contact details for WA Health Ethics and RG Offices are available from the RGS [Contacts](#) tab.

### Monitoring

The monitoring component of the RGS allow for the ongoing approval/authorisation of project utilising several forms including amendment forms, progress, final and safety report forms. These forms and their accompanying documents are submitted to the appropriate HREC and/or RG Office.

## 2 Process Flowchart



### 3 Research Resources

Before submitting a research project application all investigators should be conversant with the [National Statement on Ethical Conduct in Human Research 2023 \(National Statement\)](#), the NHMRC [Australian Code for the Responsible Conduct of Research 2007](#), the [Research Governance Policy](#) and the [Research Governance Procedures](#).

### 4 Where do I need to start in RGS?

Human research projects cannot commence at a WA Health system entity until the project has received the approval from a Human Research Ethics Committee and authorisation from the site. All research conducted at a WA Health system entity (site) must use RGS for the project.

There are a series of forms and pages that need to be completed to allow research to be conducted at a WA Health site. Not all the forms are built into a project workspace in RGS, these forms or documents are usually available on the [Documents Template](#) page of the RGS, links are provided for these throughout this document.

#### 4.1 A Project Workspace

Once you have an [RGS account](#) you can create a project workspace ([Create Project Workspace](#)).

Each research project has its own workspace, this is to ensure the confidentiality of the information associated with the project. There is a comprehensive [Help Wiki](#) to help navigate the RGS, including how to [navigate the project workspace](#).

The project workspace has links to the Help Wiki through the series of arrows in the chevron located in the header of the project workspace. Clicking on any one of the arrows will show a selection of links to the Help Wiki covering that stage of the project.

1. [Complete the Sites tab](#)

2. [Complete the Members tab](#) according to Project Members [roles](#)

3. [Complete the Declarations tab](#)

4. [Complete the Project Details tab](#)

#### 4.2 Project Workspace Security

Access to the project workspace is by invitation, this is how the security of the project is maintained. Project members can only access the project workspace by accepting the invitation, for the Ethics and Research Governance staff is by their HREC or site being added to the project. Committee Members access is by invitation to the meeting where the project will be reviewed and for Hospital Administrators it is by invitation through a research governance form.

#### 4.3 Project Workspace tabs

The project workspace has a series of tabs under the project header that contain the information for the project. For a new project the top row tabs are used from left to right. Refer to the [Help Wiki Navigate the project workspace](#) for more information including the functions of the different tabs.

Sites	Members	Project Details	Applications	Monitoring
Declarations	Comments	Letters	Publications	Summary
Timeline				

To be able to create the application forms for ethics and governance you will have to work through the first three top tabs from left to right these are:

- **Sites:** contains the sites that are covered by the HREC approval. Refer to [Help Wiki: Manage project sites](#).

- **Members:** contains all the project members involved in the project, this is the only way people not involved in reviewing the project have access to the project workspace. Refer to [Help Wiki: Manage project members](#).
- **Project Details:** there are four pages of Project Details, the information in Project Details is used in the forms within RGS, so the information is entered once and used multiple times. These pages are used for the life of the project and can be updated as required. Refer to [Help Wiki: Fill out and authorise Project Details](#).

Once these three tabs have been completed the Application tab can be accessed to create and submit the required ethics and site authorisation forms and document for review.

## 5 What else will I need to start my project?

There are several forms that may need to be completed prior to starting your application forms for ethics and governance. Not all the forms are built into a project workspace in RGS, these forms or documents are usually available on the [Documents Template](#) page of the RGS, links are provided for these throughout this document.

### 5.1 Your Profile

Each person granted access to RGS has a profile, this can be accessed by the Profile Management menu located in the left-hand menu when you are logged into RGS. Your profile has certain information that is public, other information is restricted to the HREC and Research Governance Offices and the rest can only be seen by you and an RGS Administrator.

The information that is public is your name, location, business phone number and area of speciality, ORCID ID, but only if you have agreed to publish this information (also in your profile). Additional information that is available to the HREC and Research Governance is your qualifications and expertise, GCP certification and CV (if they have been uploaded).

If you have an investigator role on a project the information you have entered in your profile under qualifications and expertise will automatically load into Project Details, page 4. Investigator Contact Information the first time it is edited after you have accepted your invitation. Once it has loaded in this section it can be edited to refine it to the project, this doesn't update your profile. This information is used in both the ethics and site forms when reviewing your role in the project.

For more information on updating your profile is available on the [Help Wiki Update your profile](#).

### 5.2 Confidentiality Disclosure Agreement

The Confidentiality Disclosure Agreement (CDA) are legal agreements that bind one or more parties to non-disclosure of confidential information and is signed by the institution. WA Health has established a standard [CDA](#) which is recommended for use in clinical trial research and data registries. The State Solicitor's Office recommends that WA Health system employees do not sign CDAs as they are legally binding agreements that can give rise to legal liability and **must** only be signed by the WA health system entity authorised signatory. This form is usually signed by all parties prior to the creation of the project workspace and can be uploaded after the workspace has been created. Please refer to the [Research Governance Procedures](#) 11.3 for further information.

### 5.3 Declaration of Confidentiality

The first form you will encounter in RGS is the [Declaration of Confidentiality](#) that accompanies the invitation to a project workspace, its terms must be agreed to by the person being invited before they can accept the invitation and gain access to the project workspace. The WA Health Declaration of Confidentiality must be agreed to by all research personnel who are non-WA Health employees accessing a project workspace. This includes research personnel with joint appointments, when the WA Health employee is conducting a project in their non-WA Health employee capacity. Refer to the [Research Governance Procedures](#) 11.2 for further information.

## 5.4 Research Conflict of Interest Form

All investigators (including those that are non-WA Health employees/students) must disclose any actual, perceived or potential conflicts of interest that may arise in relation to a proposed research project. Refer to the [Research Governance Procedures](#) 10.3 for further information. The form has to be completed by the person who has the conflict of interest. Refer to the [Help Wiki View or add a Declaration](#) for more information on how to add the form.

## 6 Which forms should be completed?

The selection of the form used is based on the type of review and access to the site is required, only one form is selected from either Ethics or Governance. Refer to the [Research Governance Procedures](#) section 4 (ethics) and 7 (governance) for further information.

Ethics Application Forms	WA HREC (WA sites only)	NMA WA HREC	NMA External HREC	NMA + Specialist HREC
Human Research Ethics Application (HREA) & WA Specific Module (WASM)	Yes	Yes	Yes	Yes
WA Health Ethics Application Form (WAHEAF)	Yes	No	No	No

Governance Application Forms	Conducting research at a site	Accessing participants, tissue, or data only
Site Specific Assessment (SSA) and Budget Form	Yes	No
Access Request (AR) Form	No	Yes

### 6.1 Human Research Ethics Application

The NHMRC's [Human Research Ethics Application](#) (HREA), is a nationally accepted ethics form. The HREA can be used for both single-centre and multi-centre projects at both a State and national level, but it is mandatory for the NMA single ethical review process. The form wasn't built into RGS so it is uploaded in the Document section of the Applications tab under the Ethics Approval section and can only be submitted if it accompanies the WA Specific Module.

### 6.2 WA Specific Module

The [WA Specific Module \(WASM\)](#) must be completed in conjunction with the HREA. The WASM addresses additional ethical issues, specific to WA that is not addressed in the HREA and must be considered when conducting human research in Western Australia. Most of the questions in the WASM will have been addressed by the completion of Project Details. If the answers in the WASM to these questions is not correct they must be updated in Project Details, the WASM will be updated the next time it is opened. The WASM can only be updated if it is in the Active section of Ethics Approval.

### 6.3 WA Health Ethics Application Form

The [WA Health Ethics Application Form \(WAHEAF\)](#) is the ethics form that is used if the research project will only be conducted within Western Australian sites. A number of the questions in the WAHEAF will have been addressed by the completion of Project Details. If the answers in the WAHEAF to these questions is not correct they must be updated in Project Details, the WAHEAF will be updated the next time it is opened. The WAHEAF can only be updated if it is in the Active section of Ethics Approval.

### 6.4 Site Specific Assessment & Budget Forms

The Site Specific Assessment (SSA) Form and associated Budget Form are governance forms to assist RGOs to assess the professional, legal and financial suitability and risk of conducting a human research project at a site.

While this form is used to gain authorisation so that a project can be conducted at a site it is important to first approach the Head of Department where the research will be conducted to get

in-principle support for the project, there can be a variety of reasons why the site is not able to accommodate a specific research project.

Sites under different HSPs can't be added to the same form as it can't be review by the different RG Offices.

If the project has multiple sites within an HSP, prior to creating any forms for site authorisation contact the [RG Office](#) associated with the sites to confirm the form that needs to be used and whether multiple sites can be added to the same form.

- **The Budget Form**

This should be completed prior to the SSA being signed. It is important that prior to inviting people, who will authorise the budget for their department, the investigators for the project have confirmation that the department can provide the service/support in the timeframe required by the protocol. For external organisations a quote for services or service agreement should be uploaded (as a document) and submitted with the Budget Form as confirmation that service provision has been agreed.

The budget has three section,

1. This first section is where the departments and external organisations involved or impacted by the research are added, this includes the Head of Department who will authorise their departments involvement.
2. The second section is where the details of the research activity at the site are added. This means the services and support required to be provided by a department and who will be conducting the research activity in that department (e.g. recruitment by staff at site or a researcher not associated with the site). External organisations are added in section one as a third-party agency where they are providing a service that would normally be provided by a department at the site to comply with the protocol, but the department can't accommodate those requirements (e.g. radiology).
3. The last section of the budget allocates the funding for the service/support and this can be funding (monetary support) or in-kind (by the site or by another organisation). For more information on how to complete the budget please see the [Help Wiki: Budget Form](#)

If the HREC review and approval is from a WA Health HREC, the 'Ethics review' fee is only fully costed to one budget form, usually for the site sponsoring the HREC. The review fee is zero in budget forms for the same project at other WA Health sites. It is also costed as zero for any external HREC review. The 'Site processing and review' is costed once in each budget form.

Refer to the [Research Governance Procedures](#) section 8.3.2 for more information. There is an example of how to construct a budget for a project on RGS Research Governance page under [Additional Governance Information](#). There is a full list of the [Budget Categories](#) available on RGS in the Help Wiki pages.

- **Site Specific Assessment Form**

Most of the information in this form has flowed through from the Project Details pages in the project workspace. If you need to update that information you will have to do it from the Project Details pages, and it will update the next time you open the form. Once the form has been completed you will see at the bottom of section 17 the Mark Complete button this button locks section 1 to 17 of the form. Section 18.1 can now be signed by the relevant person/s once they have signed the PI can sign section 18.2. Please see the [Help Wiki on the Site Assessment Form](#) for more information.

## 6.5 Access Request Form

Once again if the project has multiple sites within an HSP, prior to creating any forms for site authorisation contact the [RG Office](#) associated with the sites to confirm the form that needs to be used and whether multiple sites can be added to the same form.

Sites under different HSPs can't be added to the same form as it can't be review by the different RG Offices.

The Access Request (AR) Form is a governance form to assist RGOs to assess whether to allow access to:

- Potential participant where recruitment is through displaying posters, distributing leaflets and handouts, and a letter of invitation to potential participants (but does not involve direct recruitment of participants)
- Distribution of surveys and questionnaires to personnel of the site by e-mail, in line with the site policies (but not collation and analysis of responses at that site)
- Access to medical records, data or tissue held in the site collections or databases under their management, in line with ethical conditions imposed by the approving HREC (but not preparation, processing or analysis at that site).

As with the SSA form the Mark Complete button locks sections one to three. The form is then signed by the relevant person/s once they have signed the PI can sign. Please see the [Help Wiki on the Access Request Form](#) for more information.

## 7 Who can complete what application form?

While most forms can be created and edited by nearly all project member, signing and authorising the ethics and site forms is based on the role that the project members has.

Role	WAHEAF	WASM	SSA*	Budget*	AR*
CPI	Green	Green	Orange	Orange	Green
CPI Delegate	Green	Green	Orange	Orange	Orange
PI	Orange	Orange	Green	Green	Green
PI Delegate	Orange	Orange	Green	Green	Green
AI	Orange	Orange	Orange	Orange	Orange
RGM	Orange	Orange	Orange	Orange	Orange
Sponsor	Orange	Orange	Orange	Red	Orange

\* project members must have a role associated with the site to be able to access these forms

Green – create, edit, force check-in, sign and submit

Orange – create, edit

Red – No access

The CPI is the only one that can sign the WAHEAF and the PI for the site is the only one that can sign the SSA form.

## 8 What else needs to be submitted for review

Depending on the type of research and level of risk and consent you will need to submit some other document to support your application. Make sure all documents have the document name in the footer of the document. The document name is the name that will appear on the approval/authorisation letter. The document name is not necessarily the file name that the electronic (soft copy) is name (e.g. HREA not Output2358).

A research protocol MUST be submitted with the ethics application. Templates are available from the RGS [Document Templates](#) tab as a guide for investigators who do not already have a protocol for their research project.

Table A: Ethics Documents – as applicable	
<a href="#">Data Application Form</a> (for data linkage projects)	<a href="#">Peer Review</a>
Data Management Plan (for data linkage projects)	Product Information
Investigator Brochure	<a href="#">Protocol</a>
<a href="#">Participant Information Sheet and Consent Form (Master)</a>	<a href="#">Radiological Council Approval</a>
OR	Recruitment Documents (letters)
<a href="#">Participant Information Sheet (Master)</a>	Recruitment Documents (posters, advertisements)
<a href="#">Participant Consent Form (Master)</a>	Research Tools (interview outlines)
	Research Tools (questionnaires, surveys)
AND/OR	Participant Documents (identification card, diaries)
<a href="#">Participant Information Sheet and Consent Form (Site Master)*</a>	

\* A Site Master is typically used if a site or group of sites have requirements that are not usually required under the master PICF e.g. Catholic facilities with specific requirements relating to reproductive requirements.

The Research Governance Office will have access to all the forms and documents that you have submitted to under Ethics Approval in the Applications tab, so you only need to submit the site specific document related to your project to them. The table below

Table B: Site Specific Documents – as applicable	
<a href="#">Clinical Trial Research Agreements</a> OR <a href="#">Funding Agreement</a> OR <a href="#">Material Transfer Agreement</a> OR <a href="#">Data Transfer Agreement</a> AND/OR <a href="#">Service Agreement</a>	Based on the HREC approved Master (Site) Participant Information and Consent Form OR (Site) Participant Information Sheet (Site) Participant Consent Form
Budget Supporting Document	Medical Physicist Report
<a href="#">NHMRC Embryo Research Licensing Committee Licence</a>	<a href="#">Confidential Agreement</a>
<a href="#">Indemnity Form</a>	<a href="#">Office of the Gene Technology Regulator Approval</a>
<a href="#">Insurance Certificate of Currency</a>	<a href="#">Reproductive Technology Council Approval</a>
Insurance Policy	Institutional Biosafety Committee Notification

Submit all documents to be distributed through the sites with your application that will have the addition of a site logo and/or contact information, for example:

- posters, leaflets or handouts
- letters of invitation (on research site letterhead)
- surveys and questionnaires.

Access to data must be approved in accordance with the WA Health [Information Use and Disclosure Policy](#).

## 9 Who is the application submitted to?

When you make a submission the form/s and document/s will move from the Active section to the Submitted section in the Applications tab. Once a form or document has been submitted it forms part of the records for the HREC or Research Governance Office and can't be deleted.

### 9.1 Ethics Approval

For ethics approval who you submit your application to is dependent on the type of review and the location of the HREC. If it is a WA Health HREC then it is submitted to that HREC through the Applications tab. You will see a 'Submit to Ethics' button at the bottom right-hand side of the Ethics Approval under the Active section.

If you are submitting the application documents that have been reviewed and approved by a HREC that is part of NMA but outside WA Health then there will be a 'Submit ethics to RG Office' button in the same place. Refer to the [Research Governance Procedures](#) section 6 for more information.

All RG Offices with associated sites in the project will have access to the ethics forms and documents, so they **do not** have to be submitted again to the RG Offices.

The Help Wiki [Ethics Submission, Validation and Review Assessment](#) can step you through the submission process.

### 9.2 Site Authorisation

For site authorisation the application is submitted to the Research Governance Office (RGO) responsible for that site. You can't submit a form with multiple sites that are associated with different RGOs, it is always recommended that contact is made with the RGO associated with the



site to establish what sites can be included in a single application form. Refer to the [Research Governance Procedures](#) section 8 for more information.

The Help Wiki [Governance Submission, Validation and Review Assessment](#) can step you through the submission process.

## 10 What happens after submission?

### 10.1 Validation

When a submission is made through RGS the first step the HREC or Research Governance (RG) Office do is assess whether it is valid and ready for ethical review. The outcome of the validation will be sent to the CPI and CPI ethics submissions and the PI and PI Delegate for site authorisation submissions. The three options for a form or document are:

- Valid – the form or document will progress to the review stage.
- Additional Information Required (AIR) – change have to be made to the form or document and the new version submitted, the comments will explain what is required.
- Not Valid – the form or document may have been submitted to the wrong HREC or RG Office if this is the case contact RGS Support for assistance, you may not have to create new forms or documents. Another reason is that the document is not related to that project. The comments should clearly state why it has been marked not valid.

### 10.2 Review

Once the submission has been assessed as valid it will be submitted for review. For ethics this means that it will go to the next meeting for review by the HREC, this may also include review by a subcommittee or alternative review committee depending on the HREC terms of reference and the risk to participants associated with the project. Refer to the [Research Governance Procedures](#) sections 4, 5 and 6.

The site authorisation submission will be reviewed by a Research Governance Officer whose office is associated with the site. Refer to the [Research Governance Procedures](#) sections 7 and 8.

### 10.3 Review outcome

Once the review has been completed by either the HREC Office (for an ethics approval) or the Research Governance Office (for site authorisation) you will be informed of the outcome. Whatever the outcome of the review a letter will be sent to the relevant project members via RGS and available in the Letters tab.

You may be asked to provide more information, and this could involve the form and/or the documents you submitted for review to have the status of AIR. If a form or document is AIRed a task will be created for the responsible investigator (CPI for HREC and PI for site) and their delegate. The letter outlining what is required is automatic sent by email from RGS and maintained in the Letters tab.

If the project has received HREC approval or Site Authorisation a letter will be sent by email from RGS detailing what has been approved/authorised and the conditions of that approval/authorisation.

## 11 Research Monitoring

Once a project has obtained HREC approval from a WA Health HREC approval all further submissions to that HREC will be through the Monitoring tab. This is the same for site authorisation once it has been obtained from a site then all further submission will be through the Monitoring tab.

Sites	Members	Project Details	Applications	Monitoring
Declarations	Comments	Letters	Publications	Summary
Timeline	Administration			

## 11.1 Who can complete what monitoring forms

As shown in the table below, while most forms can be created and edited by nearly all project member, signing the form is based on the role of the project members, for the Governance Only Amendment the project member has to be associated with that site/

Role	Amendment	Progress Report	Governance Only Amendment	Amended Budget*	Safety Report*	Site Final Report	Project Final Report
CPI	Green	Green	Orange	Orange	Green	Orange	Green
CPI Delegate	Green	Green	Orange	Orange	Green	Orange	Green
PI	Green	Orange	Green	Orange	Green	Orange	Green
PI Delegate	Green	Orange	Green	Orange	Green	Orange	Green
AI	Orange	Orange	Orange	Orange	Orange	Orange	Orange
RGM	Orange	Orange	Orange	Orange	Orange	Orange	Orange
Sponsor	Orange	Orange	Orange	Red	Orange	Orange	Orange

\* project members have to have a role associated with the site to be able to access these forms

Green – create, edit, authorise and submit

Orange – create, edit

Red – No access

## 11.2 Amendment Form

This form is be used for amendments submitted to a WA Health HREC and once approved to the RG Office where sites have obtained authorisation. All supporting documents must be attached to the form.

The CPI should complete, sign and submit the amendment form to the Lead HREC (and any additional specialist HRECs) for ethics approval. Once approved, the CPI should send a copy of the approved ethics amendment form and ethics approval letter to the PIs whose sites are impacted by the amendment.

Once the form has been signed and closed, it needs to be submitted by clicking on the Submit button on the Monitoring tab

Please see the [Amendments Form](#) in the Help Wiki.

## 11.3 Governance Only Amendment Form

This form should be used by the PI for amendments submitted to an RG Office. All supporting documents should be submitted with the form.

Governance Only Amendments are amendments that have *only* governance implications with *no* ethical implications, as they involve changes to site specific governance documentation. Therefore, they do not require review by the Lead HREC (and any additional specialist HRECs) prior to submission to the RG Office. Only a small minority of amendments fall into this category (e.g. changes to project documentation, site PICF, agreements, updated insurance policy). Once the form has been signed and closed, it needs to be submitted by clicking on the Submit button on the Monitoring tab

The PI should submit the form to the RG Office, affiliated with the site, for site authorisation.

Please see the [Governance Only Amendment Form](#) in the Help Wiki.

## 11.4 Governance Only Amendment and Amended Budget Forms

When the budget needs to be amended a Governance Only Amendment Form and Amended Budget Form (ABF) are required (an ABF can't be created for a migrated project). These forms will only be submitted to the Research Governance (RG) Office responsible for that site/s. The GOA form can still reference an Amendment Form if the update is related to the GOA and ABF.

The ABF follows the same path as the Budget Form, only unlock those sections of the form that need to be updated. This is done by clicking the unlock button for the relevant department in section 2 of the form, this will revert the HoD's authorisation back to pending. Remember to update both section 2 and three of the ABF before requesting authorisation. The PI and PI

Delegate can authorise both the GOA and the ABF, which must be done before the forms can be submitted. Once the forms have been signed and closed, they need to be submitted by clicking on the Submit button on the Monitoring tab. The GOA and ABF **must always** be submitted together. If they are AIRed they will both be AIRed and must be resubmitted together.

Please see the [Amendments GOA & ABF](#) in the Help Wiki.

## 11.5 Progress Report

This report should be used by the Coordinating Principal Investigator (CPI)/CPI Delegate and Principal Investigators (PI)/PI Delegate for annual progress reports submitted to a WA Health Human Research Ethics Committee (HREC) and/or a Research Governance (RG) Office. The terms of approval for a research project require an annual (or more frequent) progress report to be submitted to both the HREC and RG Office as part of the project monitoring. The report due date in RGS is always based on the HREC approval date or the date nominated by the HREC, regardless of whether the approval was from a Lead HREC is within WA Health or a HREC under NMA.

This report must not be used to submit amendments, safety reports and final reports to the HREC or RG Office, alternative forms are available for these submissions.

**The report is divided into three sections:**

**Section 1** should be completed by the CPI or their delegate for the whole of the project. The CPI/delegate must complete Section B for the sites that they are responsible for.


**Section 2** should be completed by the PI or their delegate for their site(s).

**Section 3** should be signed by the CPI and PI or their delegates prior to submitting the report.

Please see the [Progress Reports](#) in the Help Wiki.

## 11.6 Safety Report

This report should be used by the Coordinating Principal Investigator (CPI)/CPI Delegate and Principal Investigators (PI)/PI Delegate for safety reports submitted to a WA Health Human Research Ethics Committee (HREC), a Research Governance (RG) Office or both. All supporting documents should be submitted with the report. **In WA Health, it is the CPI responsibility to ensure the submission of the report to the HREC on behalf of the sponsor.**

Safety issues in the report are broken into types. Guidance (the information icons  in the form) is given to indicate whether this type of report would *usually* require consideration and possible further action by a HREC (ethics), RG Office (governance) or both:

**If the safety issue originates from the site:** the PI or PI Delegate should complete, sign and submit the report to the RG Office responsible for the site.

**If the safety issue originates from the whole project:** the sponsor or CPI or CPI Delegate should complete the report. The CPI or CPI Delegate should sign and submit the report to the reviewing HREC(s). *If a SSI is involved, this report should be copied to the PI.* The PI should sign the copy of the report and submit the report to the RG Office.

**Definitions:**

<b>Safety Critical Adverse Events</b>	<i>Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations that should be reported to the sponsor according to the reporting requirements specified in the protocol.</i>
<b>Serious Adverse Event (SAE)/Serious Adverse Reaction (SAR)</b>	<i>Any adverse event/adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.</i>
<b>Serious Breach</b>	<i>A breach of the protocol or Good Clinical Practice (GCP) that is likely to affect to a significant degree: the safety or rights of a participant; or</i>

	<i>the reliability and robustness of the data generated in the project.</i>
<b>Significant Safety Issue (SSI)</b>	<i>A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability of the trial. Often SSIs do not fall within the definition of a Suspected Unexpected Serious Adverse Reaction (SUSAR), thus are not reported as SUSARs but require other action such as the reporting of an urgent safety measure (USM), an amendment, a temporary halt or early termination of a trial.</i>
<b>Suspected Breach</b>	<i>A report that is judged by the reporter as a possible serious breach but has yet to be formally confirmed as a serious breach by the sponsor.</i>
<b>Suspected Unexpected Serious Adverse Reaction (SUSAR)</b>	<i>An adverse reaction that is both serious and unexpected.</i>
<b>Unanticipated Serious Adverse Device Effect (USADE)</b>	<i>A serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.</i>
<b>Urgent Safety Measure (USM)</b>	<i>A measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety.</i>

Please see [Safety Reports](#) in the Help Wiki

## 11.7 Final Reports

There are two types of final reports the Site Final Report which closes a site and the Project Final Report which closes the project as a whole.

### Site Final Report

A Site Final Report is required to close the project at a WA Health site. Each site has its own form. The sites in a project have to be closed before the project itself can be closed.

Non-WA Health site/s closures information should be included in the Project Final Report, which closes the project with a WA Health HREC.

The site final report can also be used to notify the HREC if a site is to be closed prior to the expected completion date.

### Final Report for Closing the Project

The CPI or their delegate should complete the report at the completion of the research project (providing a summary of the whole project), and submit it to the reviewing HREC for consideration and approval.

Please see the [Final Reports](#) in the Help Wiki.

## 12 Research Complaint Form

This report should be used to make a complaint about:

- Project – the complaint is about a specific project that is being conducted at a WA Health site.
- RG Office – the complaint is about a Research Governance Office responsible for a site.
- HREC – the complaint is about one of the HREC sponsored by an institution that is part of WA Health.


### 1. Project:

Complaints regarding the project should be submitted to the:

- reviewing HREC if the complaint is related to the overall conduct of the research project or the research protocol; or
- relevant RG Office if the complaint is related to the conduct of the project specifically at the site.

### 2. HREC or RG Office:

Complaints regarding the research governance entity:

- 
- HREC review processes should be directed to the relevant HREC Chair outlining the grounds of concern or complaint.
  - RG Office review processes should be directed to the relevant RG Office outlining the grounds of concern or complaint.

**This form can be completed by someone other than the complainant (e.g. the HREC or RG Office on behalf of a participant) if the complaint is provided verbally. All complaints must be documented in writing.**

Once the form has been signed and closed, it needs to be submitted by clicking on the Submit button on the Monitoring tab

Please see the [Complaints](#) in the Help Wiki.