

REGGS Ethics & Governance: How-To Guides

V2
April 2022

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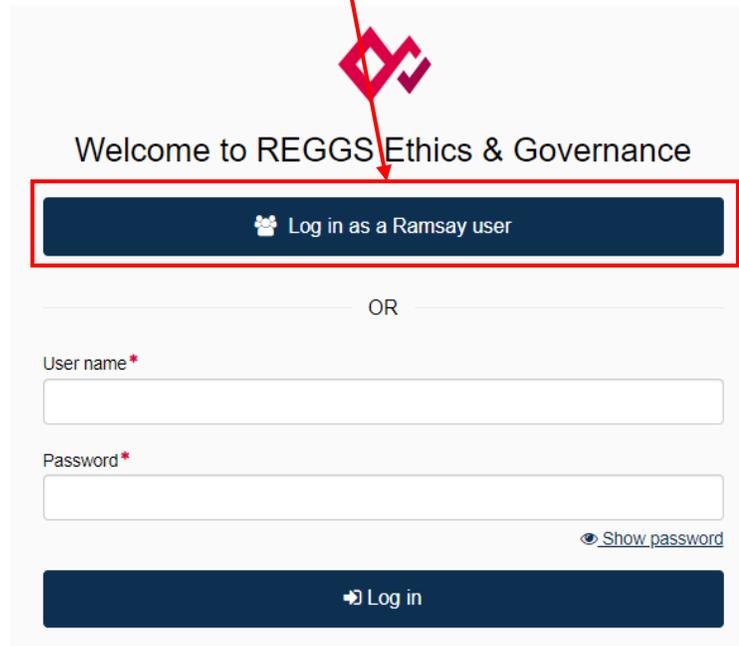
How to Create an Account and Log in

Instructions for Internal Ramsay Users

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Step 1

- Go to <https://ethicsandgovernance.ramsayhealth.com.au>
- To create an account as a Ramsay user (i.e. with a **ramsayhealth.com.au** email address), click “Log in as a Ramsay user”.
- Your account will be created automatically using your Ramsay credentials.
- Any time you wish to log in, click “Log in as a Ramsay user”.



Welcome to REGGS Ethics & Governance

[Log in as a Ramsay user](#)

OR

User name *

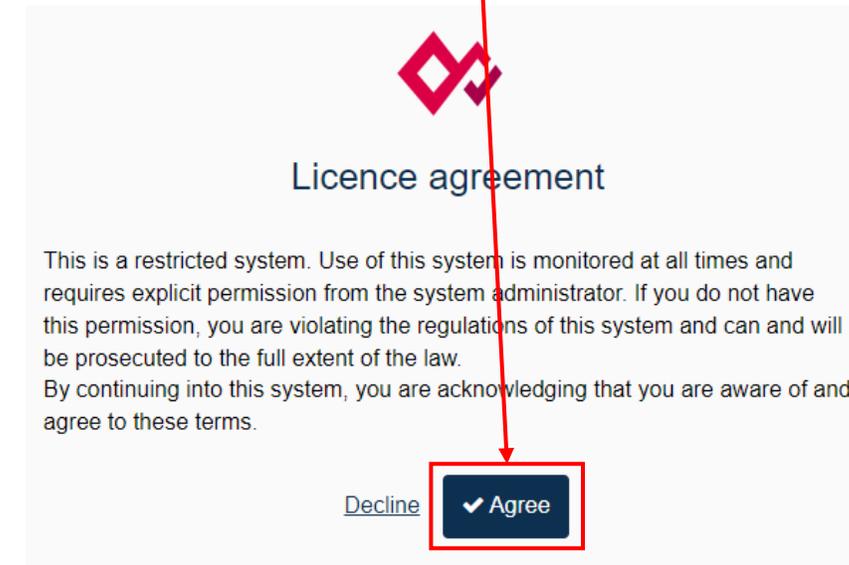
Password *

[Show password](#)

[Log in](#)

Step 2

- A “Licence agreement” notice will appear on your screen.
- Click [Agree](#)
- This will log you into your account.



Licence agreement

This is a restricted system. Use of this system is monitored at all times and requires explicit permission from the system administrator. If you do not have this permission, you are violating the regulations of this system and can and will be prosecuted to the full extent of the law. By continuing into this system, you are acknowledging that you are aware of and agree to these terms.

[Decline](#) [Agree](#)

How to Create an Account

Instructions for External (non-Ramsay) Users

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Note: If you are not using a “ramsayhealth.com.au” email address, you will be considered an External (non-Ramsay) user when logging into REGGS. You will also need to download the “Google Authenticator” app onto your smartphone

Step 1

- Go to:
<https://ethicsandgovernance.ramsayhealth.com.au>
- Click on the “Register now” link.

Welcome to REGGS Ethics & Governance



 Log in as a Ramsay user

OR

User name*

Password*

[Show password](#)

 Log in

Can't access your account? [Reset your password](#)

Don't have an REGGS Ethics & Governance account? [Register now](#)

Step 2

- Complete the relevant details and click “Register an account” button



Register an account

Email address (this will be used for your username)

First name*

Last name*

Choose a password ⓘ

Confirm your password*

I'm not a robot 

 Register an account

Already have an account? [Log in](#)

Step 3

- You will receive an email with a link to confirm your registration*.
- Please click on the link in your email to finalise the registration.



Registration Successful



Your account has been registered successfully.

Please check your email for confirmation of your registration.

 Return to logon page

Note: You cannot set up an account on behalf of another individual. External user accounts are linked to a unique Google Authenticator app on the user's device. They will need the unique Google Authenticator code generated on their mobile device each time they login.

***There may be a delay in receiving this link if you are using an institutional or University email account to register due to their firewalls. The email containing your verification link will come from “no-reply-ramsay@ramsayresearch.com.au”**

How to Log in to your Account

Instructions for External (non-Ramsay) Users

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Note: If you are not using a “ramsayhealth.com.au” email address, you will be considered an External (non-Ramsay) user when logging into REGGS. You will also need to download the “Google Authenticator” app onto your smartphone.

Step 1

If you are an external user (i.e. you are **not** using a “ramsayhealth” email address) enter your User name and password in the fields provided and click “Log in”.

Log in as a Ramsay user

OR

User name*

test@test.com.au

Password*

Show password

Log in

Can't access your account? [Reset your password](#)

Don't have an REGGS Ethics & Governance account? [Register now](#)

Step 2

Please follow the instructions provided on the screen.

- Open your Google Authenticator app
- Scan the QR code
- Enter your One Time Password
- Once you have entered your code, click “Submit”.

Manage two factor authentication

To enable two factor authentication:

1. Install the Google authenticator app on your Android or iPhone
2. Open the Google authenticator app and scan the QR code below
3. Find the one time password for the newly added account
4. Enter the one time password in the text below and click submit

One time password*

Cancel Submit

Step 3

- A “Licence agreement” notice will appear on your screen.
- Click 
- This will log you into your account.

Licence agreement

This is a restricted system. Use of this system is monitored at all times and requires explicit permission from the system administrator. If you do not have this permission, you are violating the regulations of this system and can and will be prosecuted to the full extent of the law. By continuing into this system, you are acknowledging that you are aware of and agree to these terms.

Decline Agree

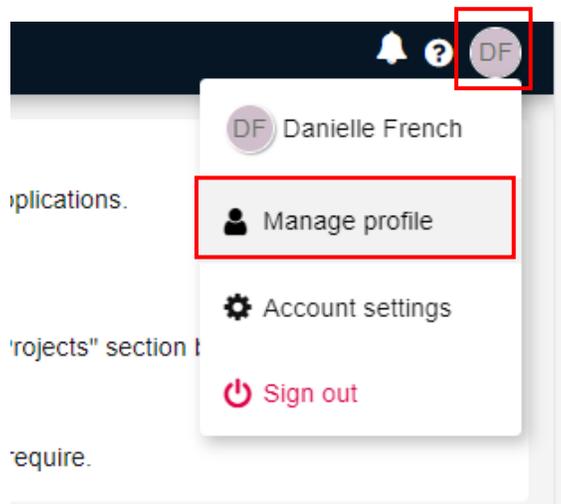


How to upload CVs and GCP certificates to your REGGS profile

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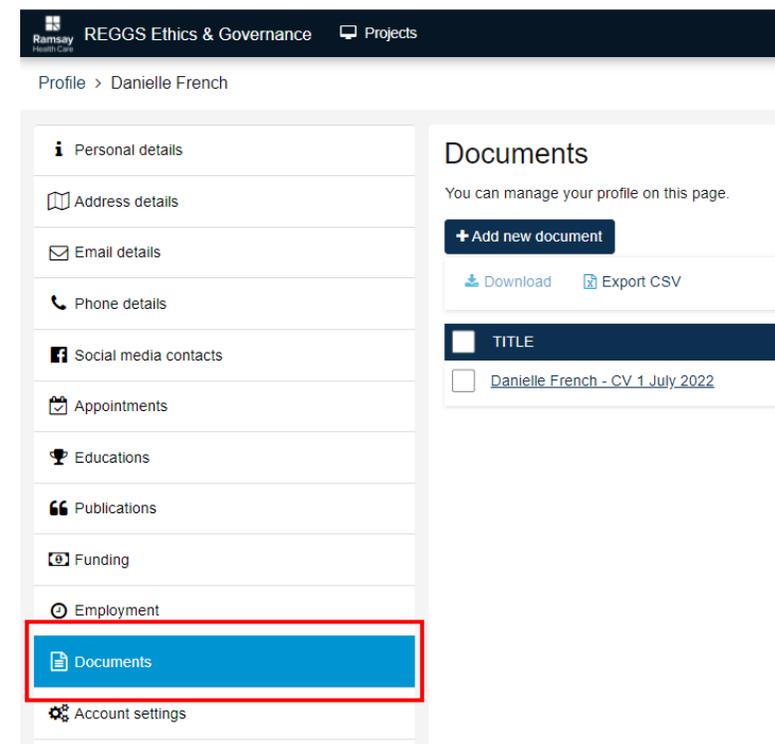
Step 1

- Log into your account
- On the top right hand corner of your screen, click on the circle containing your initials
- Go to “Manage profile”



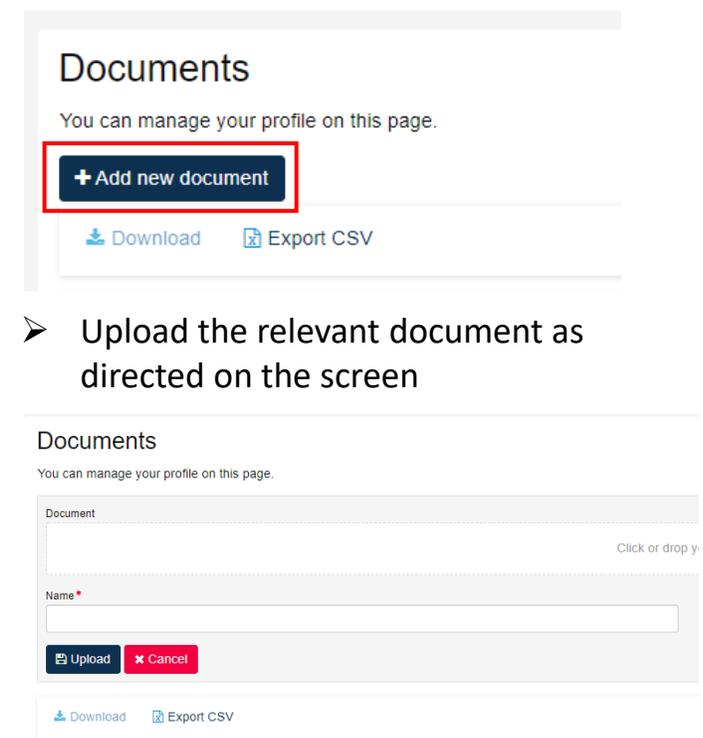
Step 2

- In the menu on the left, go to “Documents”



Step 3

- Click “Add new document” button



Note: Investigator CVs and GCP certificates must be uploaded and submitted as an attachment for every application submitted in REGGS. This is required regardless of whether a current CV/GCP certificate has been uploaded to their REGGS account or not.

For all other members of site staff (e.g. clinical trials coordinators, nursing staff, pharmacy, etc.), as long as a current CV/GCP certificate is available under their REGGS account, these documents are not required to be submitted as part of an application.

It is all trial staff responsibility to ensure their GCP qualifications are kept up-to-date. These should be renewed every three years.

How to Create a Project Registration Form

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Step 1

- After you have logged into your account, your REGGS Ethics & Governance home screen will appear.
- Go to the **“Create a form”** section on the right hand side of your screen.

Step 2

- In the “Create a form” section, click on the **+ New form** button to begin your Project Registration Form.

Ramsay Hospital Research Foundation REGGS Ethics & Governance Projects

Research Applicants
This home page will list below the 5 most recently registered projects you have access to as the application owner or permitted user. Click on the project link (e.g. 2021/PID/0001) to view project details, including associated ethics and governance applications.
To register a new project, use the "New form" button below or click on the "Projects" icon above.
To continue an in-progress registration or view/manage other registered projects not listed below, please click on the "Projects" icon in the menu bar at the top of this page or use the "View all" button in the bottom right hand corner of the "Top 5 Projects" section below.

Other users - Executives/Delegates, HREC Members, External Reviewers, etc.
Depending on your role, you may have additional icons in the bar above such as 'Decision', 'Meetings' and/or 'Review'. If you have received a notification that you have an activity to view in those areas, select the related icon to access the area you require.

Top 5 projects

| | | |
|--|------------|------------|
| 2022/PID/0005 TEST 7/01/22 | Registered | 10/01/2022 |
| 2021/PID/0052 REGGS Test 2 | Registered | 22/12/2021 |

Create a form

+ New form Project Registration

Note: You must create a Project Registration Form before you are able to prepare a HREA or SSA for your project in REGGS

For more information on the Project Registration Form, please see our **REGGS Project Registration Form - Step by Step Guide** in “Helpful Resources” section of our website: <https://www.ramsayhealth.com.au/Ramsay-Research/REGGS>

How to Edit an Ethics Application

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Step 1

- Click on the  Projects tab at the top of the homepage screen.
- Click on the hyperlinked Title of your project.

| TITLE | IDENTIFIER | STATUS | ETHICS AP... | EXPIRY DATE | ORGANISATION |
|------------------------------|---------------|------------|--------------|-------------|--------------|
| DF24.01.2022 | 2022/PID/0046 | Registered | 24/01/2022 | 25/01/2022 | REGGS |
| DF224Jan22 | 2022/PID/0047 | Registered | 24/01/2022 | 25/01/2022 | REGGS |
| x | 2022/PID/0041 | Registered | 18/01/2022 | 19/01/2022 | REGGS |

Step 2

- You will be taken to the “Applications” page.
- To edit an Ethics application, click on the hyperlinked title **which contains the code “ETH”** e.g. 2022/ETH/0039.
- This is the HREA for this project.
- You will automatically be taken into the application where you can begin editing.

Applications Details Forms Milestones More information requests

All of the relevant Ethics (HREA) and/or Governance (SSA) applications for this project can be seen in the table below. To commence or edit your applications, click on the application ID (e.g. 2022/ETH/0000) which is hyperlinked below. You may also click on the application in the "Hierarchy" diagram opposite.

To customise your view, click on "Column chooser" below. You have the option to filter, sort and hide/show columns in accordance with your preferences.

 Export CSV  Column chooser

| IDENTIFIER | TITLE | VERSION | STATUS | OWNER | CREATED D... | MODIFIED D... | RELATIONS... |
|-------------------------------|--------------------|---------|-------------|-------|--------------|---------------|--------------|
| 2022/ETH/0039 | DF24.01.2022 - ... | 1.00 | In Progress | DF | 24/01/2022 | 24/01/2022 | ↑ |
| 2022/RGO/0042 | DF24.01.2022 - ... | 1.00 | In Progress | DF | 24/01/2022 | 24/01/2022 | ↑ |

< Previous 1 Next > Page size: 10

Note: You cannot edit an application after it has been submitted.

How to Edit a Research Governance Application

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Step 1

- Click on the **Projects** tab at the top of the homepage screen.
- Click on the hyperlinked Title of your project.

| TITLE | IDENTIFIER | STATUS | ETHICS AP... | EXPIRY DATE | ORGANISATION |
|------------------------------|---------------|------------|--------------|-------------|--------------|
| DF24.01.2022 | 2022/PID/0046 | Registered | 24/01/2022 | 25/01/2022 | REGGS |
| DF224Jan22 | 2022/PID/0047 | Registered | 24/01/2022 | 25/01/2022 | REGGS |
| x | 2022/PID/0041 | Registered | 18/01/2022 | 19/01/2022 | REGGS |

Step 2

- You will be taken to the “Applications” page.
- To edit a Research Governance application, click on the hyperlinked title **which contains the code “RGO”** e.g. 2022/RGO/0042.
- This is the SSA for this project.
- You will automatically be taken into the application where you can begin editing.

Applications Details Forms Milestones More information requests

All of the relevant Ethics (HREA) and/or Governance (SSA) applications for this project can be seen in the table below. To commence or edit your applications, click on the application ID (e.g. 2022/ETH/0000) which is hyperlinked below. You may also click on the application in the "Hierarchy" diagram opposite.

To customise your view, click on "Column chooser" below. You have the option to filter, sort and hide/show columns in accordance with your preferences.

[Export CSV](#) Search... [Column chooser](#)

| IDENTIFIER | TITLE | VERSION | STATUS | OWNER | CREATED D... | MODIFIED D... | RELATIONS... |
|-------------------------------|--------------------|---------|-------------|-------|--------------|---------------|--------------|
| 2022/ETH/0039 | DF24.01.2022 - ... | 1.00 | In Progress | DF | 24/01/2022 | 24/01/2022 | ↑ |
| 2022/RGO/0042 | DF24.01.2022 - ... | 1.00 | In Progress | DF | 24/01/2022 | 24/01/2022 | ↑ |

< Previous 1 Next > Page size: 10

Note: You cannot edit an application after it has been submitted.

How to Navigate your Application using the Side Bar

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Step 1

- You do not have to answer questions sequentially in any REGGS application.
- Click on the section you wish to complete next by using the side navigation bar

(e.g. click on **Part E: Site Costing and Funding** in the left-hand side menu to go to this section).
- This will to jump to the section you wish to complete.

| | |
|---|---|
| Part A: Project-Wide Information | ✓ |
| Part B: Site Team | ✗ |
| Part C: Departments and Services | ✓ |
| Part D: Recruitment, Records, Tissue and Data | ✗ |
| Part E: Site Costing and Funding | ✗ |
| Part F: Attachments – Site Specific Documents | ✗ |
| Part G: Declaration | |

Part E: Site Costing and Funding

[← Previous](#)

E1.1. Will funding be provided to the Facility for the research activity at this site? *

Yes No

Please justify:

E1.2. Are there any financial costs to the Facility associated with the project which w

Yes No

E1.2.1. Please provide details and justify *

How to Navigate your Application using the “Next” buttons

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Step 1

Another way to navigate through your application is by clicking the **Next →** button on the Applications screen.

This will take you sequentially through the sections of your application.

The screenshot displays the application interface. On the left is a sidebar with a list of sections: Part A: Project-Wide Information (green tick), Part B: Site Team (red X), Part C: Departments and Services (green tick), Part D: Recruitment, Records, Tissue and Data (red X), Part E: Site Costing and Funding (red X), Part F: Attachments – Site Specific Documents (blue highlight, red X), and Part G: Declaration. The main content area is titled 'Part F: Attachments – Site Specific Documents'. It features a 'Previous' button, a 'Document Title' input field, a 'Document Type' dropdown menu (set to 'Ethics application (HREA or other)'), and a file upload area with a 'Drop files to attach, or browse' prompt. At the top right of the main area are 'Preview' and 'Save' buttons. At the bottom right, there is a 'Next →' button. Two red arrows originate from the text above: one points to the 'Next →' button in the top right corner, and the other points to the 'Next →' button in the bottom right corner.

Note: You are only able to use the “Next” buttons if the current section has been completed and has a green tick . If you have **not** completed a section and wish to return to it later, please refer to [“How to Navigate your Application using the Side Bar”](#)

How to Share a Project

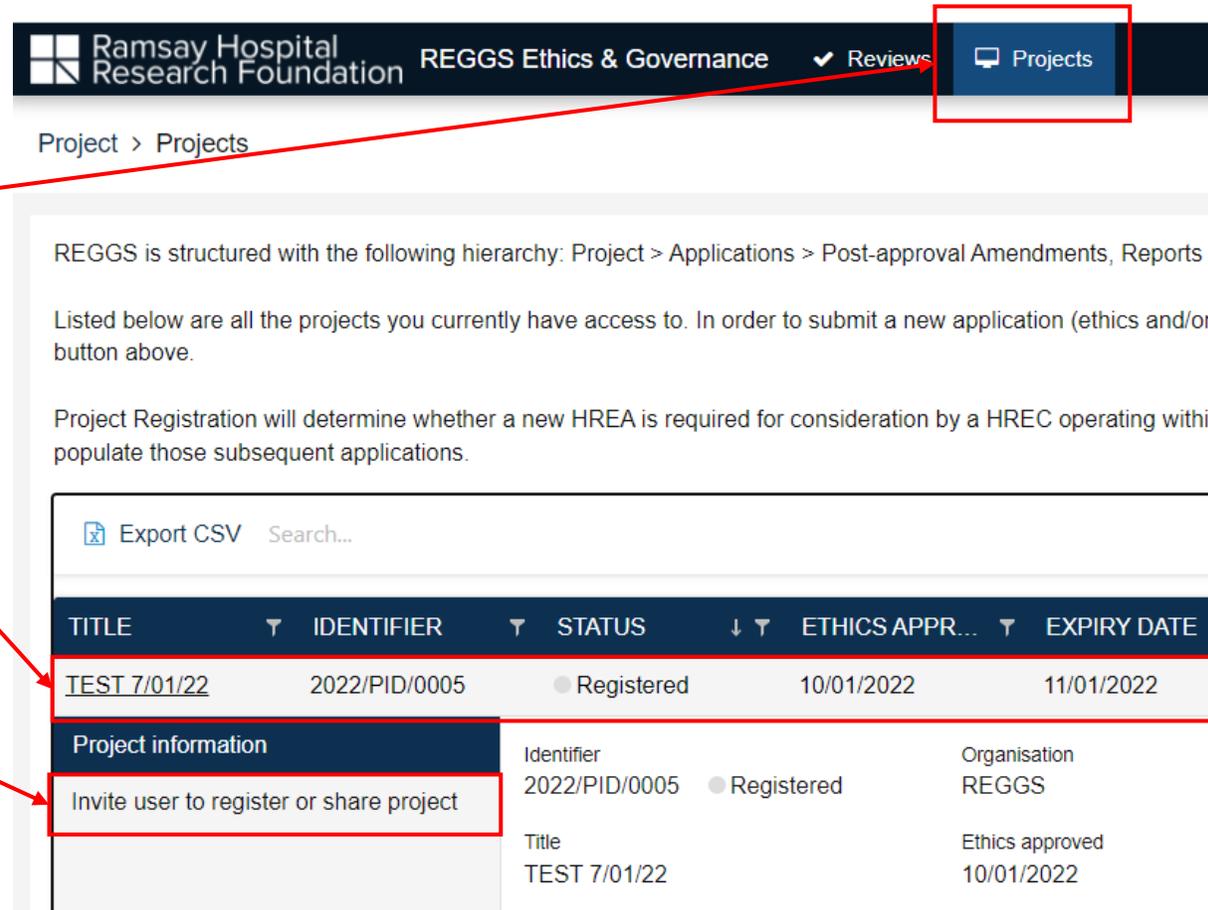
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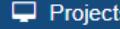
Step 1

- Click on the  Projects tab at the top of the homepage screen.
- Find the Project you wish to share (e.g. 2022/PID/0005)

Step 2

- Click anywhere in the grey bar
- The bar will expand to show more information about this Project
- Select “Invite user to register or share project”



Ramsay Hospital Research Foundation REGGS Ethics & Governance  

Project > Projects

REGGS is structured with the following hierarchy: Project > Applications > Post-approval Amendments, Reports a

Listed below are all the projects you currently have access to. In order to submit a new application (ethics and/or button above.

Project Registration will determine whether a new HREA is required for consideration by a HREC operating within populate those subsequent applications.

 Export CSV Search...

| TITLE | IDENTIFIER | STATUS | ETHICS APPR... | EXPIRY DATE |
|------------------------------|---------------|------------|----------------|-------------|
| TEST 7/01/22 | 2022/PID/0005 | Registered | 10/01/2022 | 11/01/2022 |

Project information

Invite user to register or share project

Identifier 2022/PID/0005 Registered Organisation REGGS

Title TEST 7/01/22 Ethics approved 10/01/2022

Instructions continued on next page 

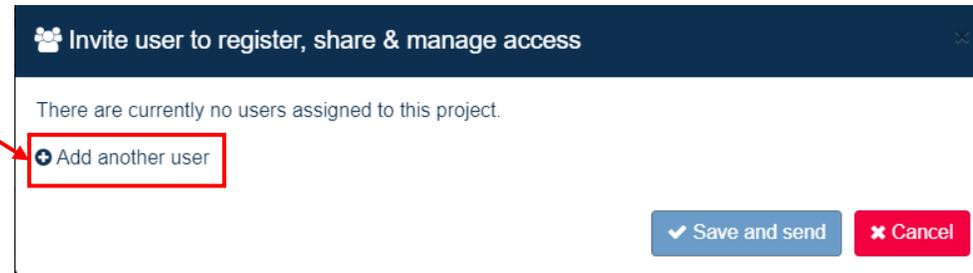
Note: In order to view or edit an application in REGGS, a user must first register for an account.

How to Share a Project (cont'd)

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Step 3

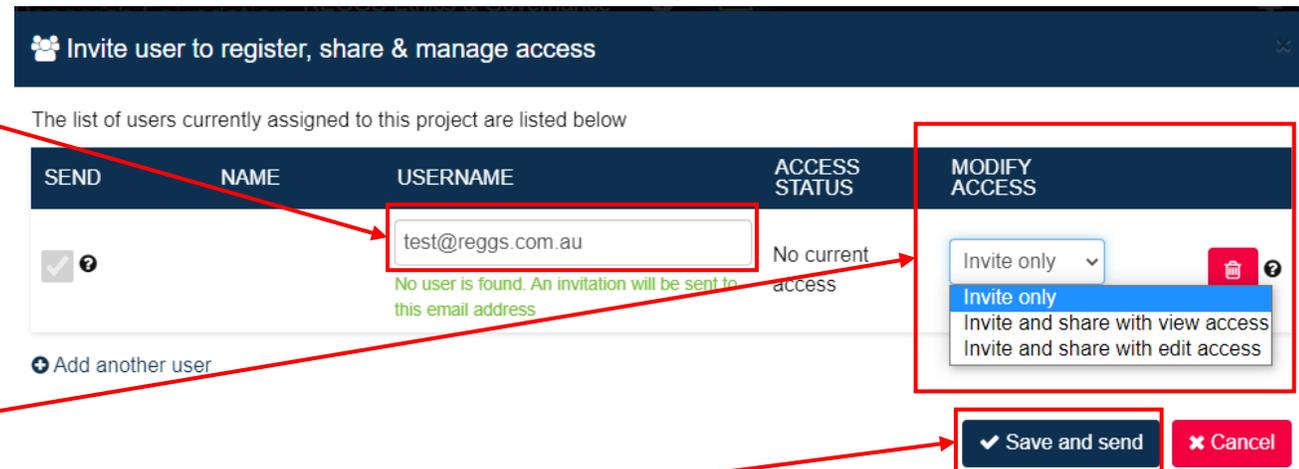
- In the pop out box, you will see any team members who already have access to this project.
- You also have the option to “Add another user”



Note: In order to view or edit a Project in REGGS, a user must first register for an account.

Step 4

- Under “Username” field, type in the email address of the person you want to share the project with.
- REGGS will recognise whether this person already has a REGGS account
 - If they do not, REGGS will invite them to create an account as well as sharing the project with them.



Step 5

- Use the dropdown menu under “Modify Access” to select what access this person should have to the project.

Step 6

- Click the “Save and send” button.
- The User(s) will be sent an email notifying them that you have shared this project with them.

How to Share an Application

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Step 1

- Click on the **Projects** tab at the top of the homepage screen.
- Click on the hyperlinked Title of your project.

| TITLE | IDENTIFIER | STATUS | ETHICS AP... | EXPIRY DATE | ORGANISATION |
|------------------------------|---------------|------------|--------------|-------------|--------------|
| DF24.01.2022 | 2022/PID/0046 | Registered | 24/01/2022 | 25/01/2022 | REGGS |
| DF224Jan22 | 2022/PID/0047 | Registered | 24/01/2022 | 25/01/2022 | REGGS |
| x | 2022/PID/0041 | Registered | 18/01/2022 | 19/01/2022 | REGGS |

Step 2

- You will be taken to the “Applications” page.
- Find the Application you wish to share (e.g. 2022/ETH/0039)
- Click anywhere in the grey bar
- The bar will expand to show more information about this Application.
- Select “Invite user to register or share application”

Applications Details Forms Milestones More information requests

All of the relevant Ethics (HREA) and/or Governance (SSA) applications for this project can be seen in the table below.

To commence or edit your applications, click on the application ID (e.g. 2022/ETH/0000) which is hyperlinked below. You may also click on the application in the "Hierarchy" diagram opposite.

To customise your view, click on "Column chooser" below. You have the option to filter, sort and hide/show columns in accordance with your preferences.

[Export CSV](#) [Column chooser](#)

| IDENTIFIER | TITLE | VERSION | STATUS | OWNER | CREATE... | MODIFIED D... | RELATIONS... |
|-------------------------------|--------------------|---------|-------------|-------|------------|---------------|--------------|
| 2022/ETH/0039 | DF24.01.2022 - ... | 1.00 | In Progress | DF | 24/01/2022 | 24/01/2022 | ↑ |

Application information

| | | | | |
|------------|---------------------|-------------|-------|----|
| Identifier | 2022/ETH/0039 | In Progress | Owner | DF |
| Title | DF24.01.2022 - HREA | | Users | DF |
| Version | 1 | | | |

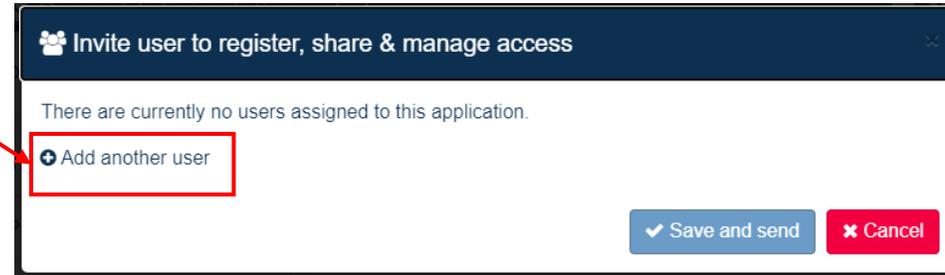
Instructions continued on next page

How to Share an Application (cont'd)

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Step 3

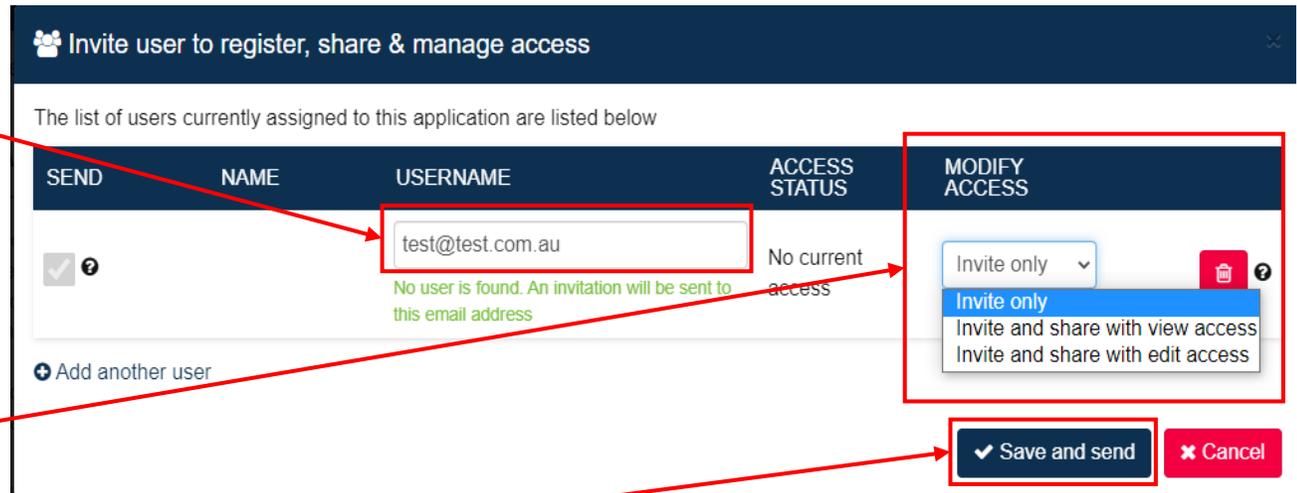
- In the pop out box, you will see any team members who already have access to this application.
- You also have the option to “Add another user”



Note: In order to view or edit an application in REGGS, a user must first register for an account.

Step 4

- Under “Username” field, type in the email address of the person you want to share the application with.
- REGGS will recognise whether this person already has a REGGS account
 - If they do not, REGGS will invite them to create an account as well as sharing the application with them.



Step 5

- Use the dropdown menu under “Modify Access” to select what access this person should have to the Application.

Step 6

- Click the “Save and send” button.
- The User(s) will be sent an email notifying them that you have shared this application with them.

How to Submit your Application

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Step 1

- Check your application is complete by looking at the side bar menu on the left-hand side of the screen.
- If the section is complete, it will have a green tick

Step 2

- Once your application is complete, click “Complete” (e.g. Complete SSA or Complete HREA).
- This will lodge your application.

Note: Only the Ramsay Coordinating Principal Investigator (CPI) is able to submit a HREA, and only the Site Principal Investigator (PI) is able to submit an SSA in REGGS. **This process replaces a signature.**

If you cannot see the “Complete” button, it may be because you are not listed in the Application with one of these roles.

*To share an existing application with the Chief Investigator, please refer to **“How to Share an application”** instructions.*

The screenshot shows a web application interface. On the left is a vertical sidebar menu with items: Part A: Project-Wide Information (green tick), Part B: Site Team (green tick), Part C: Departments and Services (green tick), Part D: Recruitment, Records, Tissue and Data (green tick), Part E: Site Costing and Funding (green tick), Part F: Attachments – Site Specific Documents (red cross), and Part G: Declaration (blue background). A red arrow points from the 'Part G: Declaration' item in the sidebar to the main content area. The main content area is titled 'Part G: Declaration' and contains a 'Previous' button, a question G1.1 with radio buttons for 'Yes' and 'No', a question G2, and a list of 8 numbered items. At the bottom of the form is a 'Complete SSA' button, which is highlighted with a red box. A red arrow points from the 'Complete SSA' button back to the 'Step 2' text box above. In the top right of the form area are 'Preview' and 'Save' buttons.

Instructions continued on next page

How to Submit your Application (cont'd)

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Step 3

- After you have submitted your application, you have the option to download a copy of all application forms and attachments.
- To download these documents, click on the .zip link.

Step 4

- Your submission is now complete.
- You can now click “Close” or close your browser.

Application submission

Select the application attachments you wish to download:

[All application forms and attachments \(.zip\)](#)

This package of files contains your application content, attachments, and other files supporting your application.

> Next

Application submission

The application **2022/RGO/0058** has been successfully generated.

Your application has been successfully submitted. Thank you for your application. To continue please click the close button.

< Back X Close

Note: You will automatically be sent a copy of your application as an attachment in your “Confirmation of submission” email.

How to Delete your Application

Step 1

- Click on the **Projects** tab at the top of the homepage screen.
- Click on the hyperlinked title of your project.

| TITLE | IDENTIFIER | STATUS |
|------------------------------|---------------|------------|
| DF24.01.2022 | 2022/PID/0046 | Registered |
| DF224Jan22 | 2022/PID/0047 | Registered |
| x | 2022/PID/0041 | Registered |

Step 2

- You will be taken to the "Applications" page.
- Find the Application you wish to delete (e.g. 2022/ETH/0039)
- Click anywhere in the grey bar
- The bar will expand to show more information about this Application.
- Select "Delete application"

Applications Details Forms Milestones More information

All of the relevant Ethics (HREA) and/or Governance (SSA) applications for To commence or edit your applications, click on the application ID (e.g. 2022 "Hierarchy" diagram opposite.

To customise your view, click on "Column chooser" below. You have the opti

[Export CSV](#) Search...

| IDENTIFIER | TITLE | VERSION | STATUS |
|-------------------------------|--------------------|---------|-------------|
| 2022/ETH/0039 | DF24.01.2022 - ... | 1.00 | In Progress |

Application information

- Identifier: 2022/ETH/0039 In Progress
- Title: DF24.01.2022 - HREA
- Version: 1

[Delete application](#)

Step 3

- You will be prompted to confirm you want to delete your application, as this cannot be reversed.
- If yes, click the "Delete" button.

Delete application

The selected application will be deleted. Are you sure you want to delete it?

This action cannot be undone.

[Delete](#) [Cancel](#)

Note: You are only able to delete applications which have not yet been submitted.

If you wish to withdraw a submitted application, please contact us.

How to delete a draft Project Registration form

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Step 1

- Under “Projects” list, find the draft Project Registration form you wish to delete.
- Click anywhere on the grey bar to expand the project information
- Click the “Delete form” option.

Ramsay Hospital Research Foundation REGGS Ethics & Governance ✓ Reviews Projects

Project > Projects

REGGS is structured with the following hierarchy: Project>>>Applications>>>Post-approval/authorisation A
In order to submit an application (ethics and/or site-governance), you must first register the project - you ca

Project Registration will determine whether a new HREA is required for consideration by a HREC operating
registration pre-populate those subsequent applications.

Export CSV Search...

| TITLE | IDENTIFIER | STATUS | ETHICS AP... | EXPIRY D |
|---------------------------------------|----------------------|-------------|--------------|----------|
| 068576 - Project R... | | In Progress | | |
| Invite user to register or share form | | | | |
| Delete form | | | | |
| Identifier | 068576 | Owner | DF | |
| Title | Project Registration | | | |

Step 2

- A pop-up box will appear, warning you that the delete cannot be undone and asking you if you want to continue.
- If you wish to proceed, click “Delete form”

Delete form

The form will be deleted. Are you sure you want to continue?

This action cannot be undone.

Delete form Cancel

Note: Forms cannot be deleted once they have been submitted. If you wish to withdraw or edit a submitted application, please contact us.

How to add a New Site to an existing Research Governance Application

[Back to Contents](#)

Step 1

- Click on the **Projects** tab at the top of the homepage screen.
- Click on the hyperlinked title of your project.

Step 2

- You will be taken to the “Applications” page.
- Click on the **+New Site** button

Step 3

- Complete and submit the **Addition of New Research Site/s** form which will appear on a new screen.
- This will generate an SSA application for the new site to complete and submit

The screenshot shows the Ramsay Hospital Research Foundation REGGS Ethics & Governance interface. At the top, the 'Projects' tab is highlighted with a red box. Below it, the breadcrumb 'Project > Projects' is visible. The main content area shows a list of projects with columns: TITLE, IDENTIFIER, STATUS, ETHICS APPR..., EXPIRY DATE, ORGANISATION, FUNDS INVOICED, and FUNDS REMAINING. The first row is 'TEST' with identifier '2022/PID00002' and status 'Registered'. A red box highlights the 'TEST' title. Below the table, the 'Applications' tab is selected and highlighted with a red box. Underneath, there is a '+ New Site' button, also highlighted with a red box. The bottom part of the screenshot shows another table with columns: IDENTIFIER, TITLE, VERSION, STATUS, OWNER, CREATED DATE, and MODIFIED DATE. The first row is '2022/RGO00001' with title 'TEST - Attadale R...', version '1.00', status 'In Progress', and owner 'DF'.

| TITLE | IDENTIFIER | STATUS | ETHICS APPR... | EXPIRY DATE | ORGANISATION | FUNDS INVOICED | FUNDS REMAINING |
|-------|---------------|------------|----------------|-------------|--------------|----------------|-----------------|
| TEST | 2022/PID00002 | Registered | 30/01/2022 | 31/01/2022 | REGGS | | \$0.00 |

| IDENTIFIER | TITLE | VERSION | STATUS | OWNER | CREATED DATE | MODIFIED DATE |
|-------------------------------|----------------------|---------|-------------|-------|--------------|---------------|
| 2022/RGO00001 | TEST - Attadale R... | 1.00 | In Progress | DF | 30/01/2022 | 30/01/2022 |

How to submit a Research Governance Amendment

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Step 1

- Click on the **Projects** tab at the top of the homepage screen.
- Click on the hyperlinked title of your project.

Step 2

- You will be taken to the “Applications” page.
- Click on the hyperlinked identifier of your application (e.g. 2022/RGO/0058)

Instructions continued
on next page

Ramsay Hospital Research Foundation REGGS Ethics & Governance **Projects**

Project > Projects

REGGS is structured with the following hierarchy: Project > Applications > Post-approval Amendments, Reports and Safety Notifications.

Listed below are all the projects you currently have access to. In order to submit a new application (ethics and/or governance), you must first register the project by completing a Project Registration Form. Your Project Registration will determine whether a new HREA and/or SSA will be needed for your research to be undertaken at any Ramsay sites. The details entered at Project Registration will help to pre-populate your applications.

[Export CSV](#)

| TITLE | IDENTIFIER | STATUS | ETHICS APPR... | EXPIRY DATE | ORGANISATION | FUNDS INVOICED | FUNDS REMAINING |
|----------------------|--------------|------------|----------------|-------------|--------------|----------------|-----------------|
| TEST | 2022/PID0002 | Registered | 30/01/2022 | 31/01/2022 | REGGS | | \$0.00 |

Project > 2022/PID/0069 - TEST

Applications Details More information requests

All of the relevant Ethics (HREA) and/or Governance (SSA) applications for this project can be seen in the table below. To commence or edit your applications, click on the application ID (e.g. 2022/ETH/0000) which is hyperlinked below. You may also click on the application in the "Hierarchy" diagram opposite.

To customise your view, click on "Column chooser" below. You have the option to filter, sort and hide/show columns in accordance with your preferences.

[+ New Site](#)

[Export CSV](#) [Column chooser](#)

| IDENTIFIER | TITLE | STATUS | CREATED DATE | MODIFIED DATE | VERS... |
|-------------------------------|-------|--------------|--------------|---------------|---------|
| 2022/RGO/0058 | TEST | ● Authorised | 11/02/2022 | 18/03/2022 | 1.00 |

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How to submit a Research Governance Amendment (cont'd)

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Step 3

- You will see that the pathway at the top of the screen has updated. You should see and you are now in your selected Application.
- Click on “**Forms**” tab at the top of your screen

The screenshot shows the top navigation bar with the Ramsay Health Care logo and the text 'REGGS Ethics & Governance'. A secondary navigation bar contains a 'Projects' icon. Below this, a breadcrumb path is displayed: 'Project > 2022/PID/0069 - TEST > 2022/RGO/0058 - TEST'. The 'Forms' tab in the main navigation is highlighted with a red box. Below the navigation, there is a text block: 'All of the relevant Ethics (HREA) and/or Governance (SSA) applications for this project can be seen in the table below. To commence or edit your applications, click on the application ID (e.g. 2022/ETH/0000) which is hyperlinked below. You may also see the application ID in the table below.' A red arrow points from the 'Forms' tab in the navigation to the 'Forms' tab in the breadcrumb path.

Step 4

- In the “**Forms**” tab, click on the **+ New form** button.
- Depending on whether or not you have already submitted an amendment for this project, the **+New Form** button will either be in the **middle** or in the **top right hand corner** of your screen

The screenshot shows the same breadcrumb path as in Step 3. The '+ New form' button is highlighted with a red box in the top right corner of the main content area. Below the navigation, there is a text block: 'All of the relevant Ethics (HREA) and/or Governance (SSA) applications for this project can be seen in the table below. To commence or edit your applications, click on the application ID (e.g. 2022/ETH/0000) which is hyperlinked below. You may also see the application ID in the table below.' A red arrow points from the '+ New form' button in the navigation to the '+ New form' button in the main content area.

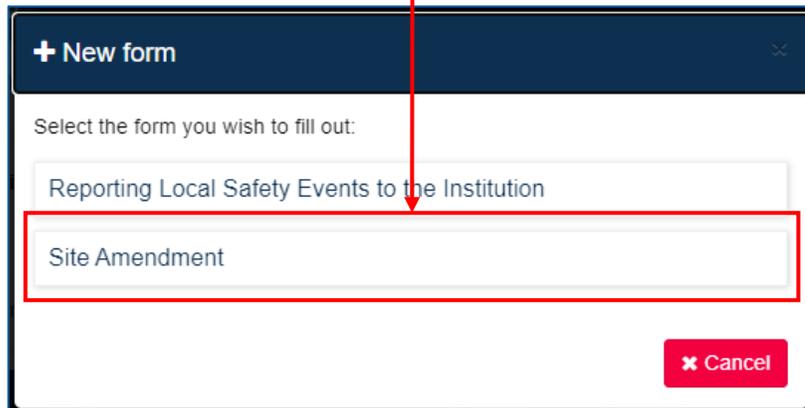
Instructions continued
on next page

How to submit a Research Governance Amendment (cont'd)

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Step 5

- Select "Site Amendment" from the menu



+ New form

Select the form you wish to fill out:

Reporting Local Safety Events to the Institution

Site Amendment

✕ Cancel

Step 6

- Review the information and follow the instructions on the screen
- At the bottom of the "Project Details and Site Amendment Type" page, select the appropriate Amendment Type for your project from the dropdown menu provided

Select Amendment Type*

The types of amendment that can be submitted to the RGO are:

- General amendment
- Addition of a site
- CPI change notification
- PI change notification
- Extension of HREC approval notification
- Change site investigators or site administration contacts
- Change to contracts

Show Detailed Description of Amendment Types



Unsure which amendment type to choose?

Refer to our [Tips for Research Governance Amendments](#) slide for help

Next →

Step 7

- Follow the prompts on the screen and answer all relevant questions before submitting your application.

Note: Once your RG amendment has been reviewed, you will receive either an approval notification or a request for further information via email.

Uploading Documents for your Research Governance Amendment

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For General Amendments, you have the option to upload study documents in two places:

- 1 Under **General Site Amendment** in **Site Specific Document Upload** section
 - This is for **site specific documents only** (e.g. site specific PICFs).
 - Click “Add Another” to add a document.

- 2 In the **Ethics Approved Documents** section.
 - This is for **master documents approved by your HREC only** (e.g. Master PICFs, protocols, IBs, etc.)
 - Click “Add Another” to add a document.

Site Specific Document Upload

- This section allows the applicant to submit amended versions of documents already authorised by the Site or to submit new documents.
- If there are no documents to be uploaded select the checkbox and the '-' icon and progress to the next section.
- A tracked copy of a changed/updated document is required to be uploaded to allow the RGO to easily identify the changes made. Please upload one tracked copy of each new version of a document.

Only upload site documents to be reviewed by the Site/RGO.
If Ethics exists in REGGS all Ethics approved documents (listed on the Ethics approval letter) have been made visible to the Site/RGO
If Ethics exists outside of REGGS you will be guided to upload the Ethics approval email/letter AND the approved documents in a separate section “Ethics Approved Document Upload”.

Am I uploading as a new version Yes/No?
Yes when the document you are submitting to the Site/RGO already exists in the system.
e.g a Site Specific Participant Information Form that has previously been authorised.

No when you want to upload a new document that does not have a previous version already existing in the system. note: studies that have been migrated from a legacy system will have Site/RGO authorised documents but they may not yet be available to update in REGGS, in this case No should be selected.

Upload a new version
 Upload a new document

Document Upload
Upload only site specific documents here e.g. site PISCF. If there are no site documents select the checkbox and then the minus icon.

+ Add Another

Ethics Approved Document Upload

Project Details and Site Amendment Type ✓
General Site Amendment ✓
Ethics Approved Document Upload
Details for Invoices
Declaration

Preview Validate Save
Previous Next
Upload the ethics approval and approved documents as a .zip or .msg
+ Add Another
Previous Next

Tips for Research Governance Amendments

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Amendment Types

You have the option to submit the following types of Site amendments in REGGS:

- **Addition of a site**
To be used when you want to add a new site to an existing project
- **CPI change notification**
To be used when the Ramsay CPI on your project has changed
- **PI change notification**
To be used when the PI for your site has changed
- **Extension of HREC approval notification**
To be used when you have received confirmation from your HREC that your project oversight has been extended
- **Change site investigators or site administration contacts**
To be used when you wish to add / remove study team members from your application
- **Change to contracts**
To be used when you have an updated contract relating to your project
- **General amendment**
To be used for all other amendments, including document updates and reports

Note: Safety Reports are submitted separately and not as amendments

Minor vs Major Amendments - Examples

Certain Governance amendment attract fees, depending on whether they are considered to be Major. **Below are some examples of different types of applications which constitute a Major or Minor Amendment:**

MAJOR

- Change to PI
- Change to CPI
- Change to contract
- General amendment which increases the burden on participants and/or is expected to impact patient safety/ put the patients at higher risk;
- General amendment which results in an increase to site workload (e.g. staff are required to conduct additional research activities not within the scope of the original project)
- General amendment with a significant change to the design of the protocol

MINOR

- Extension of HREC approval
- General amendment with minor update to the protocol which does not add to patient burden
- General amendment with minor update to the protocol which doesn't impact site workload
- Addition of a site (*N.B. This is not charged as an amendment; it is charged as a new submission. The fee for this will depend on the type of study and number of sites participating.*)
- General amendment which involves a slight change to eligibility criteria
- General amendment which includes updates to Site Specific PICFs of an administrative nature
- General amendment with routine updates to Investigator Brochures and/or other product information

For the list of our current fees, please visit <https://www.ramsayhealth.com.au/Ramsay-Research/Research-Governance/Fees>

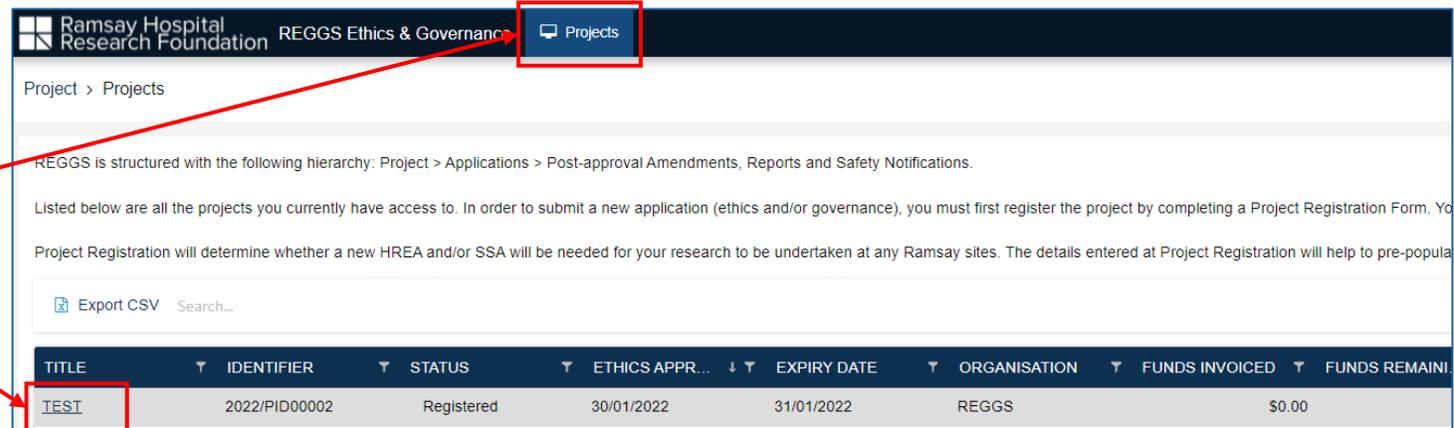


How to submit a Local Safety Report in REGGS

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Step 1

- Click on the **Projects** tab at the top of the homepage screen.
- Click on the hyperlinked title of your project.



Ramsay Hospital Research Foundation REGGS Ethics & Governance **Projects**

Project > Projects

REGGS is structured with the following hierarchy: Project > Applications > Post-approval Amendments, Reports and Safety Notifications.

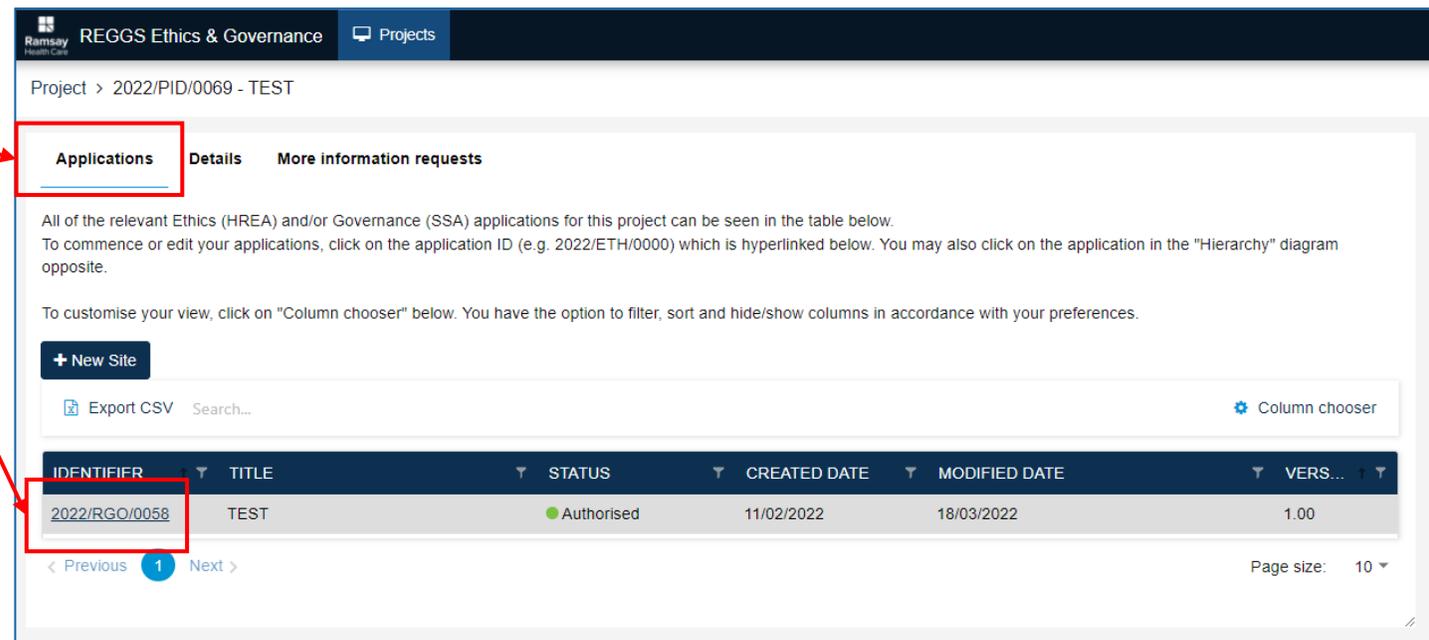
Listed below are all the projects you currently have access to. In order to submit a new application (ethics and/or governance), you must first register the project by completing a Project Registration Form. Your Project Registration will determine whether a new HREA and/or SSA will be needed for your research to be undertaken at any Ramsay sites. The details entered at Project Registration will help to pre-populate your applications.

[Export CSV](#)

| TITLE | IDENTIFIER | STATUS | ETHICS APPR... | EXPIRY DATE | ORGANISATION | FUNDS INVOICED | FUNDS REMAINING |
|----------------------|--------------|------------|----------------|-------------|--------------|----------------|-----------------|
| TEST | 2022/PID0002 | Registered | 30/01/2022 | 31/01/2022 | REGGS | | \$0.00 |

Step 2

- You will be taken to the “Applications” page.
- Click on the hyperlinked identifier of your application (e.g. 2022/RGO/0058)



Ramsay Health Care REGGS Ethics & Governance **Projects**

Project > 2022/PID/0069 - TEST

Applications Details More information requests

All of the relevant Ethics (HREA) and/or Governance (SSA) applications for this project can be seen in the table below. To commence or edit your applications, click on the application ID (e.g. 2022/ETH/0000) which is hyperlinked below. You may also click on the application in the "Hierarchy" diagram opposite.

To customise your view, click on "Column chooser" below. You have the option to filter, sort and hide/show columns in accordance with your preferences.

[+ New Site](#)

[Export CSV](#) [Column chooser](#)

| IDENTIFIER | TITLE | STATUS | CREATED DATE | MODIFIED DATE | VERS... |
|-------------------------------|-------|--------------|--------------|---------------|---------|
| 2022/RGO/0058 | TEST | ● Authorised | 11/02/2022 | 18/03/2022 | 1.00 |

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Instructions continued
on next page

How to submit a Local Safety Report in REGGS (cont'd)

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Step 3

- You will see that the pathway at the top of the screen has updated to include the ID for your selected Application.
- Click on **“Forms”** tab at the top of your screen

The screenshot shows the top navigation bar with 'Ramsay Health Care' and 'REGGS Ethics & Governance' on the left, and 'Projects' on the right. Below the navigation bar, a breadcrumb path is displayed: 'Project > 2022/PID/0069 - TEST > 2022/RGO/0058 - TEST'. Below the breadcrumb, there are five tabs: 'Applications', 'Details', 'Forms', 'Milestones', and 'More information requests'. The 'Forms' tab is highlighted with a red box. Below the tabs, there is a paragraph of text: 'All of the relevant Ethics (HREA) and/or Governance (SSA) applications for this project can be seen in the table below. To commence or edit your applications, click on the application ID (e.g. 2022/ETH/0000) which is hyperlinked below. You may also click on the appli opposite.'

Step 4

- In the **“Forms”** tab, click on the **+ New form** button.
- Depending on whether or not you have already submitted an amendment for this project, the **+New Form** button will either be in the **middle** or in the **top right hand corner** of your screen

The screenshot shows the same breadcrumb path as in Step 3. Below the breadcrumb, there are five tabs: 'Applications', 'Details', 'Forms', 'Milestones', and 'More information requests'. The 'Forms' tab is highlighted with a red box. Below the tabs, there is a search bar with the text 'Export CSV' and a magnifying glass icon. Below the search bar, there is a table with the following columns: 'TITLE', 'STATUS', 'OWNER', and 'CREATED DATE'. The table contains one row of data: '068938 - Site Amendment', 'Approved', 'Danielle French', and '25/03/2022'. In the top right corner of the screen, there is a dark blue button with a white plus sign and the text '+ New form', which is highlighted with a red box.

Instructions continued on next page

How to submit a Local Safety Report in REGGS (cont'd)

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Step 5

- Select "Reporting Local Safety Events to the Institution" from the menu

+ New form

Select the form you wish to fill out:

- Reporting Local Safety Events to the Institution
- Site Amendment

✕ Cancel

Step 6

- Select the Type of Safety Report you wish to report from the dropdown menu
- Complete each section of the Safety Report and submit

Ramsay Health Care REGGS Ethics & Governance

Form > Reporting Local Safety Events to the Institution

Project details

Document Upload

Declaration

Project Title TEST

Sponsor

Site Reference No. 2022/RGO/0058

Site Hollywood Private Hospital

Principal Investigator Danielle French

Type of Safety Report

- SSI from approving HREC (external to Ramsay)
- Local Safety Event (SUSAR/USAE/URSAE)

Preview Save

Next →

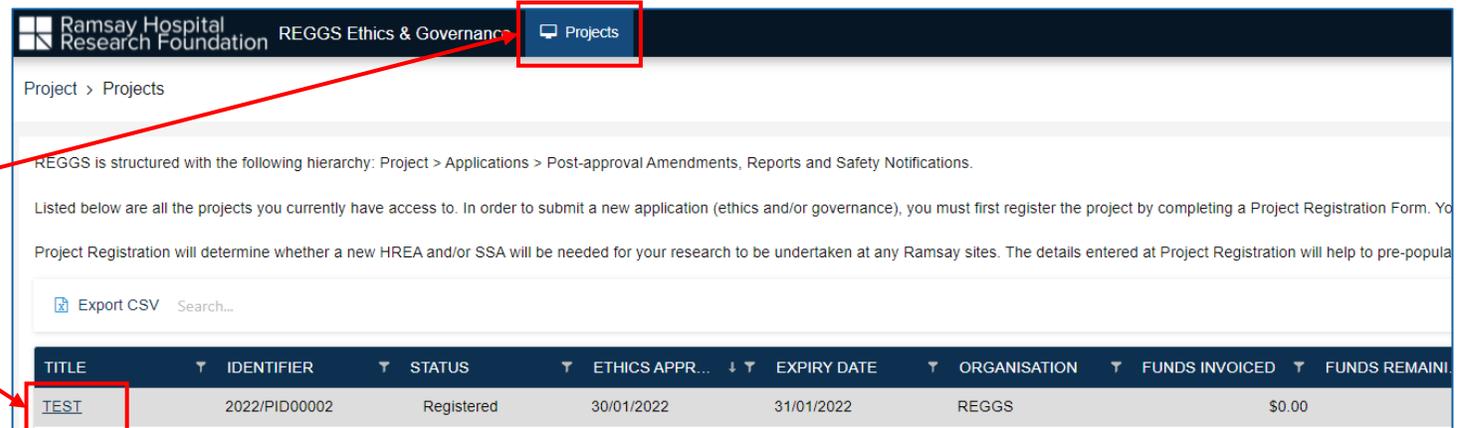


How to locate an “In Progress” Amendment or Safety Report in REGGS

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Step 1

- Click on the **Projects** tab at the top of the homepage screen.
- Click on the hyperlinked title of your project.



Ramsay Hospital Research Foundation REGGS Ethics & Governance **Projects**

Project > Projects

REGGS is structured with the following hierarchy: Project > Applications > Post-approval Amendments, Reports and Safety Notifications.

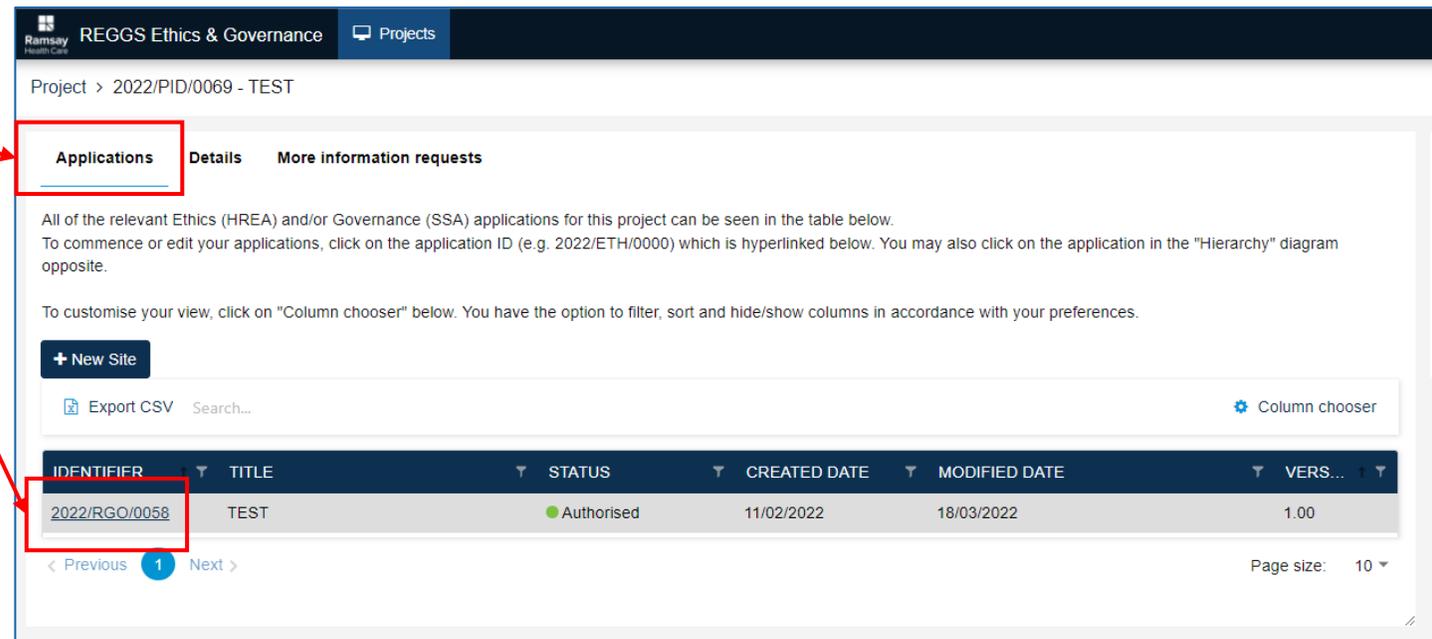
Listed below are all the projects you currently have access to. In order to submit a new application (ethics and/or governance), you must first register the project by completing a Project Registration Form. Your Project Registration will determine whether a new HREA and/or SSA will be needed for your research to be undertaken at any Ramsay sites. The details entered at Project Registration will help to pre-populate your applications.

[Export CSV](#)

| TITLE | IDENTIFIER | STATUS | ETHICS APPR... | EXPIRY DATE | ORGANISATION | FUNDS INVOICED | FUNDS REMAINING |
|----------------------|--------------|------------|----------------|-------------|--------------|----------------|-----------------|
| TEST | 2022/PID0002 | Registered | 30/01/2022 | 31/01/2022 | REGGS | | \$0.00 |

Step 2

- You will be taken to the “Applications” page.
- Click on the hyperlinked identifier of your application (e.g. 2022/RGO/0058)



Ramsay Health Care REGGS Ethics & Governance **Projects**

Project > 2022/PID/0069 - TEST

Applications Details More information requests

All of the relevant Ethics (HREA) and/or Governance (SSA) applications for this project can be seen in the table below. To commence or edit your applications, click on the application ID (e.g. 2022/ETH/0000) which is hyperlinked below. You may also click on the application in the "Hierarchy" diagram opposite.

To customise your view, click on "Column chooser" below. You have the option to filter, sort and hide/show columns in accordance with your preferences.

[+ New Site](#)

[Export CSV](#) [Column chooser](#)

| IDENTIFIER | TITLE | STATUS | CREATED DATE | MODIFIED DATE | VERS... |
|-------------------------------|-------|--------------|--------------|---------------|---------|
| 2022/RGO/0058 | TEST | ● Authorised | 11/02/2022 | 18/03/2022 | 1.00 |

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Instructions continued
on next page

How to locate an “In Progress” Amendment or Safety Report in REGGS

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Step 3

- You will see that the pathway at the top of the screen has updated to include the ID for your selected Application.
- Click on “Forms” tab at the top of your screen

The screenshot shows the top navigation bar with 'Ramsay Health Care' and 'REGGS Ethics & Governance'. Below it, a breadcrumb path is displayed: 'Project > 2022/PID/0069 - TEST > 2022/RGO/0058 - TEST'. A red box highlights this path. Below the breadcrumb, there are several tabs: 'Applications', 'Details', 'Forms', 'Milestones', and 'More information requests'. The 'Forms' tab is highlighted with a red box. Below the tabs, there is a paragraph of text: 'All of the relevant Ethics (HREA) and/or Governance (SSA) applications for this project can be seen in the table below. To commence or edit your applications, click on the application ID (e.g. 2022/ETH/0000) which is hyperlinked below. You may also click on the appli opposite.'

Step 4

- You will now see all Approved, Submitted, or In Progress amendments related to this application in the table at the bottom section of the screen

The screenshot shows the same breadcrumb path: 'Project > 2022/PID/0069 - TEST > 2022/RGO/0058 - TEST'. Below the breadcrumb, there are several tabs: 'Applications', 'Details', 'Forms', 'Milestones', and 'More information requests'. The 'Forms' tab is highlighted with a red box. Below the tabs, there is a search bar with 'Export CSV' and a search icon. Below the search bar, there is a table with the following data:

| TITLE | STATUS | OWNER | CREATED DATE | MODIFIED DATE | SUBMITTED DATE |
|--|-------------|-----------------|--------------|---------------|----------------|
| 068938 - Site Amendment | Approved | Danielle French | 25/03/2022 | 25/03/2022 | 25/03/2022 |
| 068987 - Reporting Local Safety Event... | In Progress | Danielle French | 06/04/2022 | 06/04/2022 | |
| 068939 - Site Amendment | Submitted | Danielle French | 25/03/2022 | 29/03/2022 | 29/03/2022 |

Step 5

- To continue an “In Progress” application, click on the hyperlinked title of the form.



How to download forms and attachments once they are submitted

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Step 1

- Locate your approved project
- Click on Forms Tab

Project > 2022/PID/0069 - TEST > 2022/RGO/0058 - TEST + New form

Applications Details **Forms** Milestones More information requests

Export CSV

| TITLE | STATUS | OWNER | CREATED DATE | MODIFIED DATE | SUBMITTED DATE |
|---------------------------|-----------|-----------------|--------------|---------------|----------------|
| ⋮ 068938 - Site Amendment | Approved | Danielle French | 25/03/2022 | 25/03/2022 | 25/03/2022 |
| ⋮ 068939 - Site Amendment | Submitted | Danielle French | 25/03/2022 | 29/03/2022 | 29/03/2022 |
| ⋮ 068940 - Site Amendment | Submitted | Danielle French | 25/03/2022 | 25/03/2022 | 25/03/2022 |

Step 2

- Locate the form you have submitted
- Click on the three dots on the left hand side

Project > 2022/PID/0069 - TEST > 2022/RGO/0058 - TEST + New form

Applications Details **Forms** Milestones More information requests

Export CSV

| TITLE | STATUS | OWNER | CREATED DATE | MODIFIED DATE | SUBMITTED DATE |
|-------|-----------|-----------------|--------------|---------------|----------------|
| ⋮ | Approved | Danielle French | 25/03/2022 | 25/03/2022 | 25/03/2022 |
| ⋮ | Submitted | Danielle French | 25/03/2022 | 29/03/2022 | 29/03/2022 |

Step 3

- Click "Download Attachments" button
- Your documents will download as a .zip file



- **What is the Project Registration form? Why do I need it?**

- The Project Registration Form collects basic information about your project and will help REGGS to decide whether you need a HREA and/or SSA. The Project Registration form helps to link applications and provides a better way of managing multi-site projects.

- **Why do I have to download Google Authenticator?**

- REGGS uses Google Authenticator for Multi-Factor Authentication (MFA) (also known as “2-Step Verification”).
- If you are an External user (i.e. not using a “ramsayhealth” email address), in addition to your password, you’ll also need to enter a code generated by the Google Authenticator app in order to log into your account.

- **Why do I have to use Google Authenticator?**

- REGGS uses Google Authenticator for Multi-Factor Authentication (MFA) (also known as “2-Step Verification”).
- MFA means a user must provide a two or more pieces of evidence to verify their identity (e.g. a password and a code) in order to gain access to an app or digital resource. MFA is an important data security feature.

- **How do I use Google Authenticator?**

- Go to the App Store on your smartphone and search for “Google Authenticator”. Download the app onto your device. It is free to download.
- Follow the instructions outlined in “[How to Log in to your Account - Instructions for External \(non-Ramsay\) Users](#)”.

- **I have a technical issue with REGGS. Who do I contact?**

- For technical issues, please use our queries portal [here](#).
- Alternatively, please contact the team on REGGS@ramsayhealth.com.au.

- **How do I add a new research team member in REGGS?**

- You can submit a “Change site investigators or site administration contacts” amendment in REGGS. Please see [How to submit a Research Governance Amendment](#) and [Tips for Research Governance Amendments](#) for instructions

