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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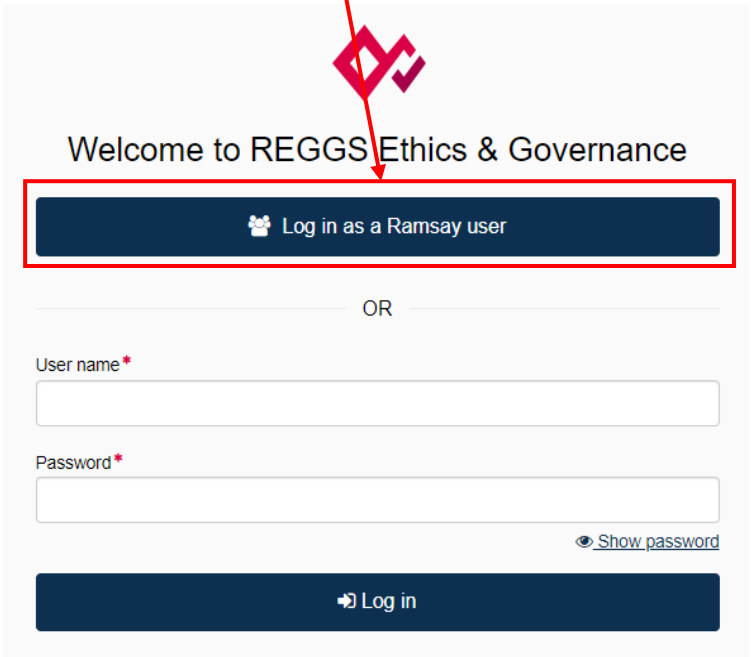
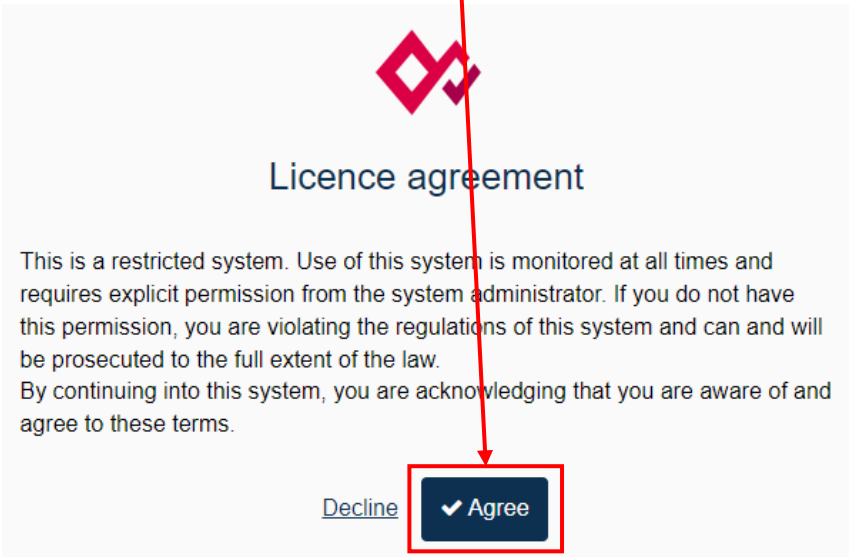
Step 1

- 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".



Step 2

- A "Licence agreement" notice will appear on your screen.
- Click ✔ Agree
- This will log you into your account.



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How to Create an Account

Instructions for External (non-Ramsay) Users

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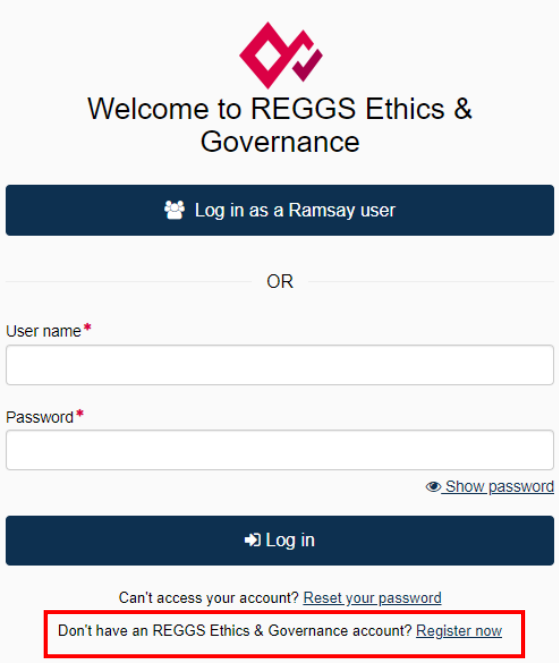
Note: If you are not using a "ramsayhealth.com.au" email address, you will be considered an External (non-Ramsay) user when logging into REGGS. You will also need to download the "Google Authenticator" app onto your smartphone

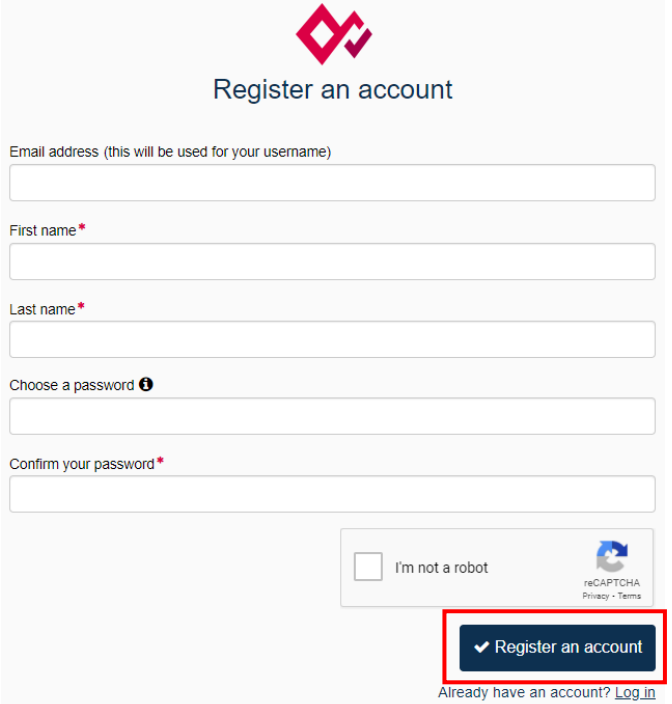
Step 1

- Go to: https://ethicsandgovernance.ramsayhealth.com.au
- Click on the "Register now" link.



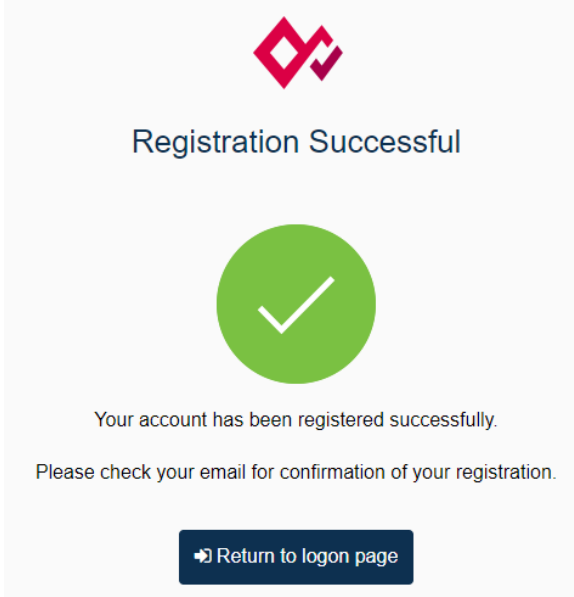
Step 2

- Complete the relevant details and click "Register an account" button



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.



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**"*

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How to Log in to your Account

Instructions for External (non-Ramsay) Users

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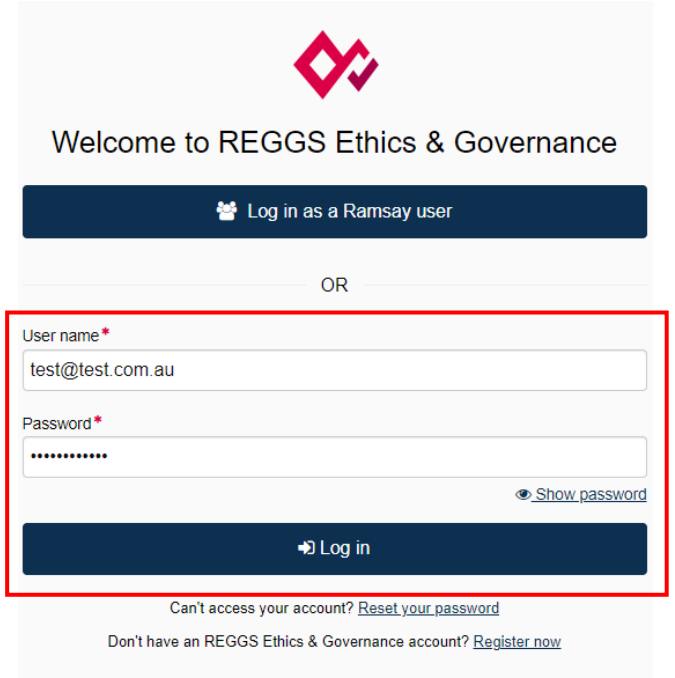
Note: If you are <u>not</u> using a "ramsayhealth.com.au" email address, you will be considered an External (non-Ramsay) user when logging into REGGS. You will also need to download the "Google Authenticator" app onto your smartphone.

Step 1

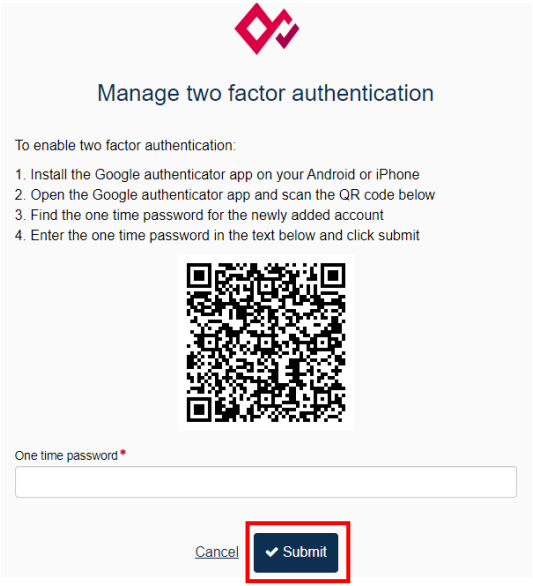
If you are an external user (i.e. you are **<u>not</u>** using a "ramsayhealth" email address) enter your User name and password in the fields provided and click "Log in".



Step 2

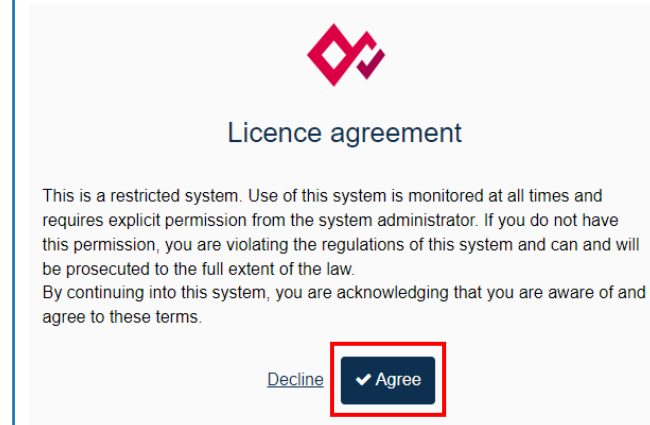
Please follow the instructions provided on the screen.

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



Step 3

- A "Licence agreement" notice will appear on your screen.
- Click ✔ Agree
- This will log you into your account.



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How to upload CVs and GCP certificates to your REGGS profile

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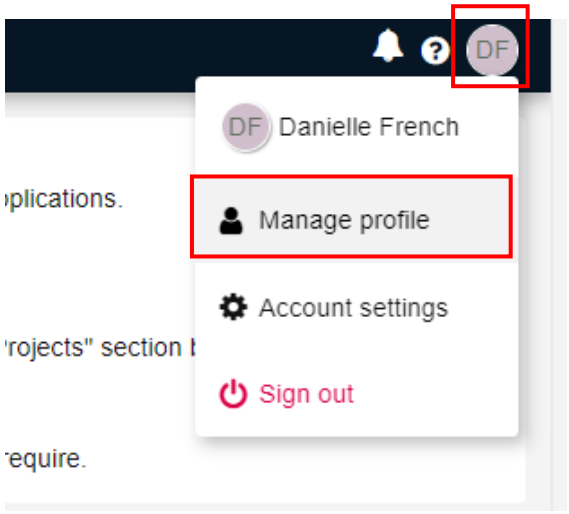
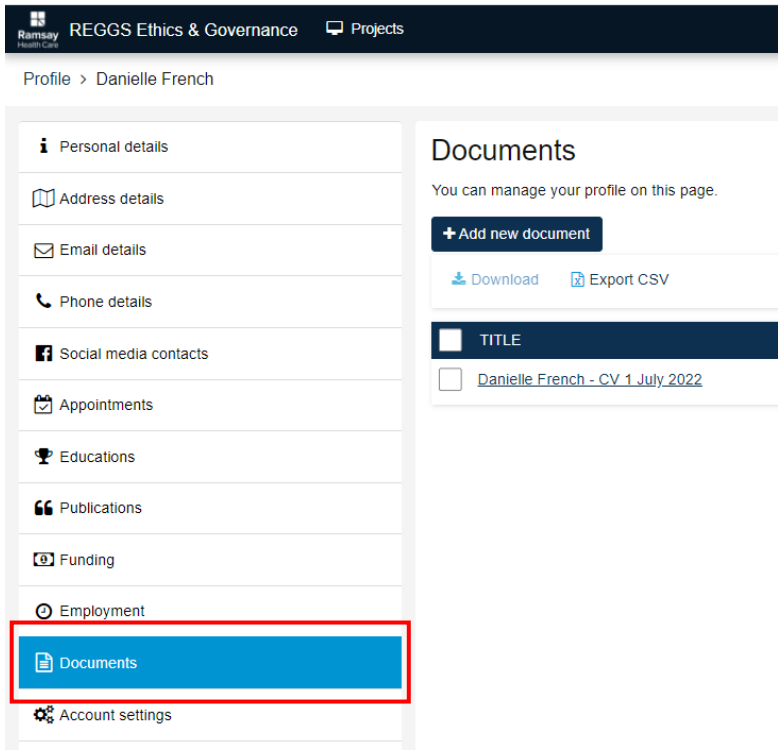
Step 1

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



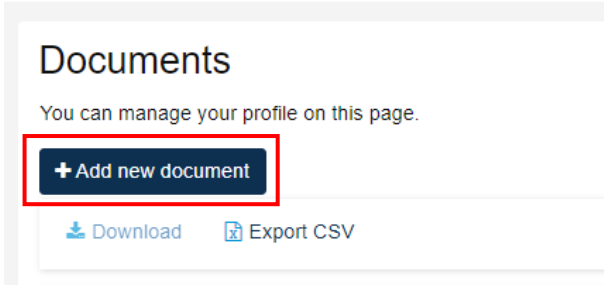
Step 2

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

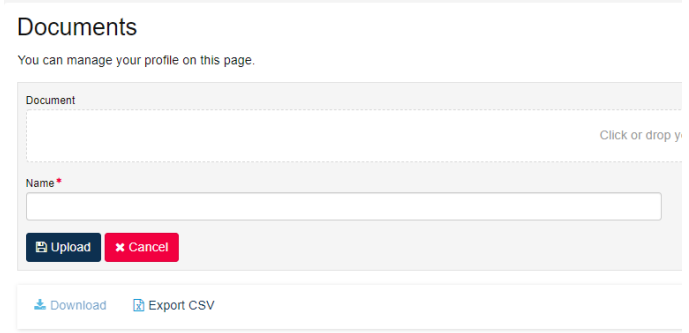


Step 3

- Click “Add new document” button



- Upload the relevant document as directed on the screen



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.

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How to Create a Project Registration Form

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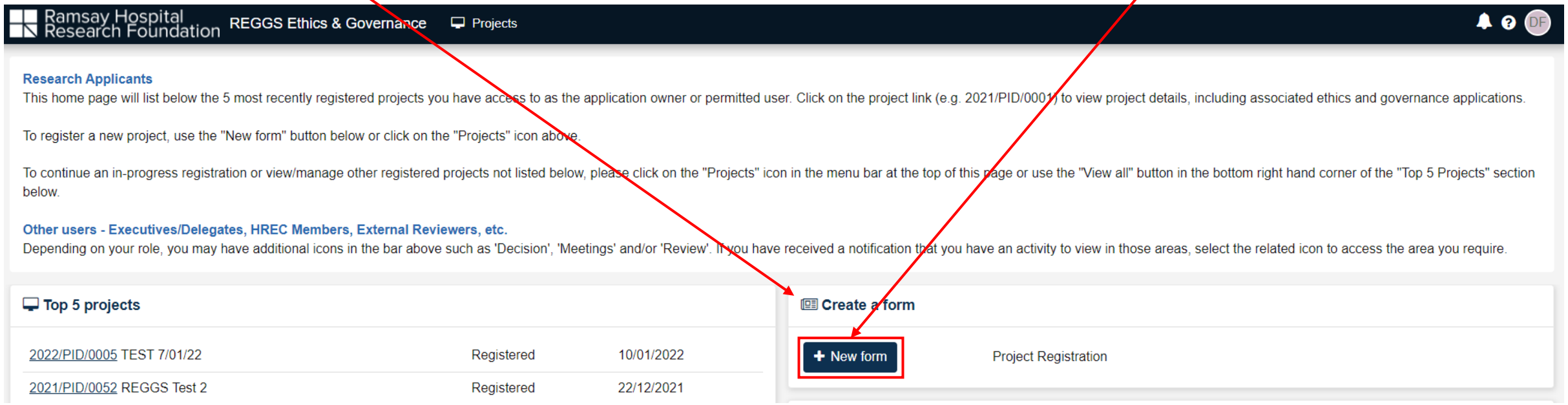
Step 1

- 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.



***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*

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How to Edit an Ethics Application

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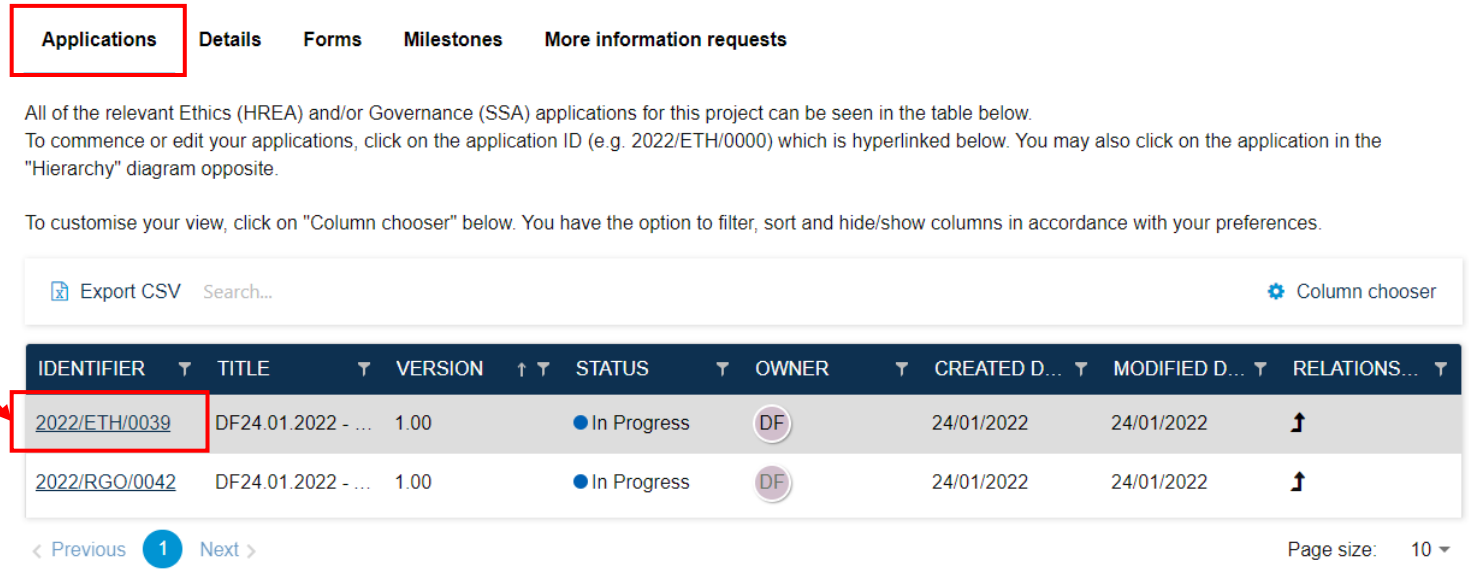
Step 1

- 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 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.*

Ramsay Health Care

How to Edit a Research Governance Application

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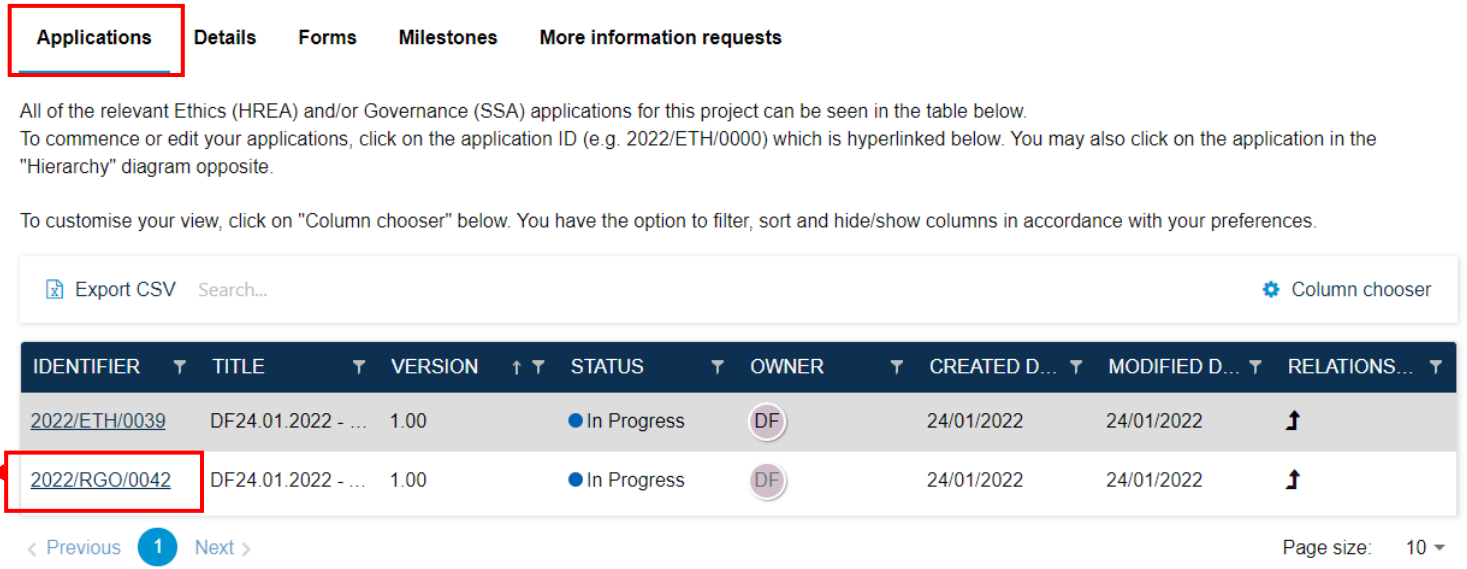
Step 1

- 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.*

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How to Navigate your Application using the Side Bar

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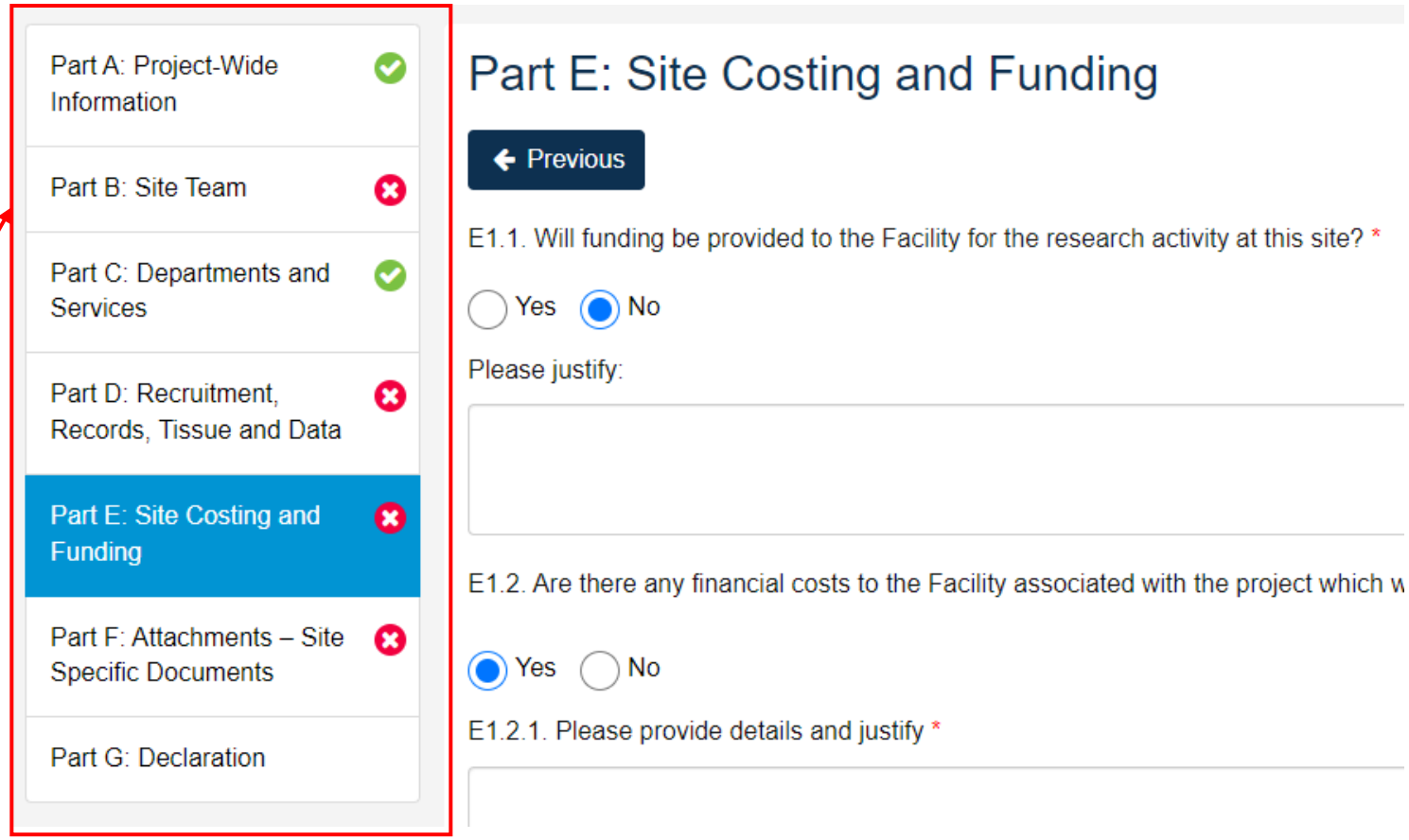
Step 1

- 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.



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How to Navigate your Application using the “Next” buttons

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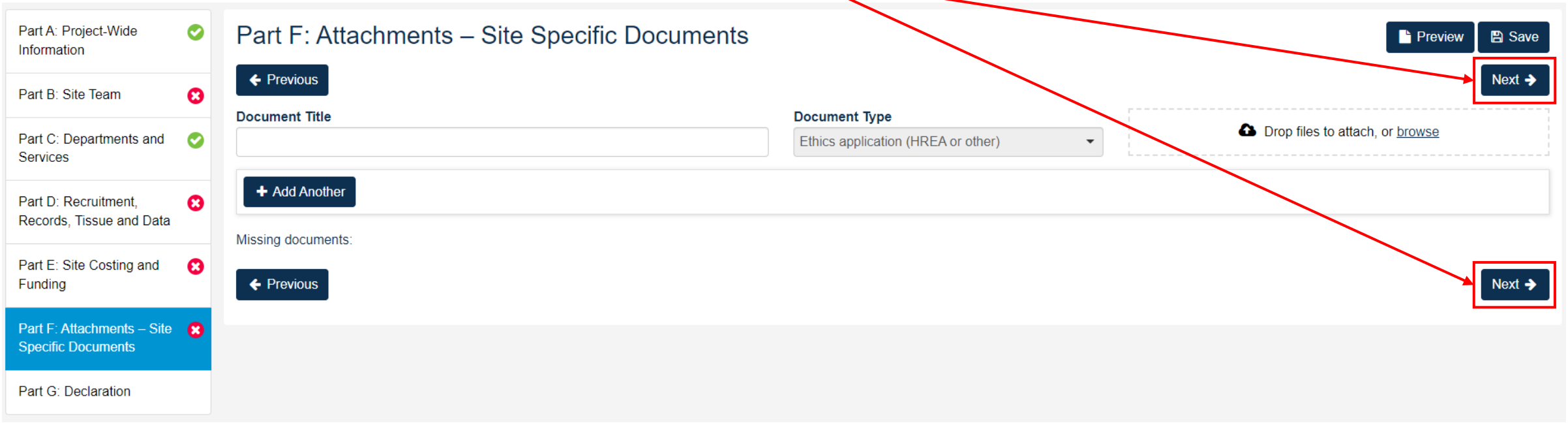
Step 1

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.



***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**”*

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How to Share a Project

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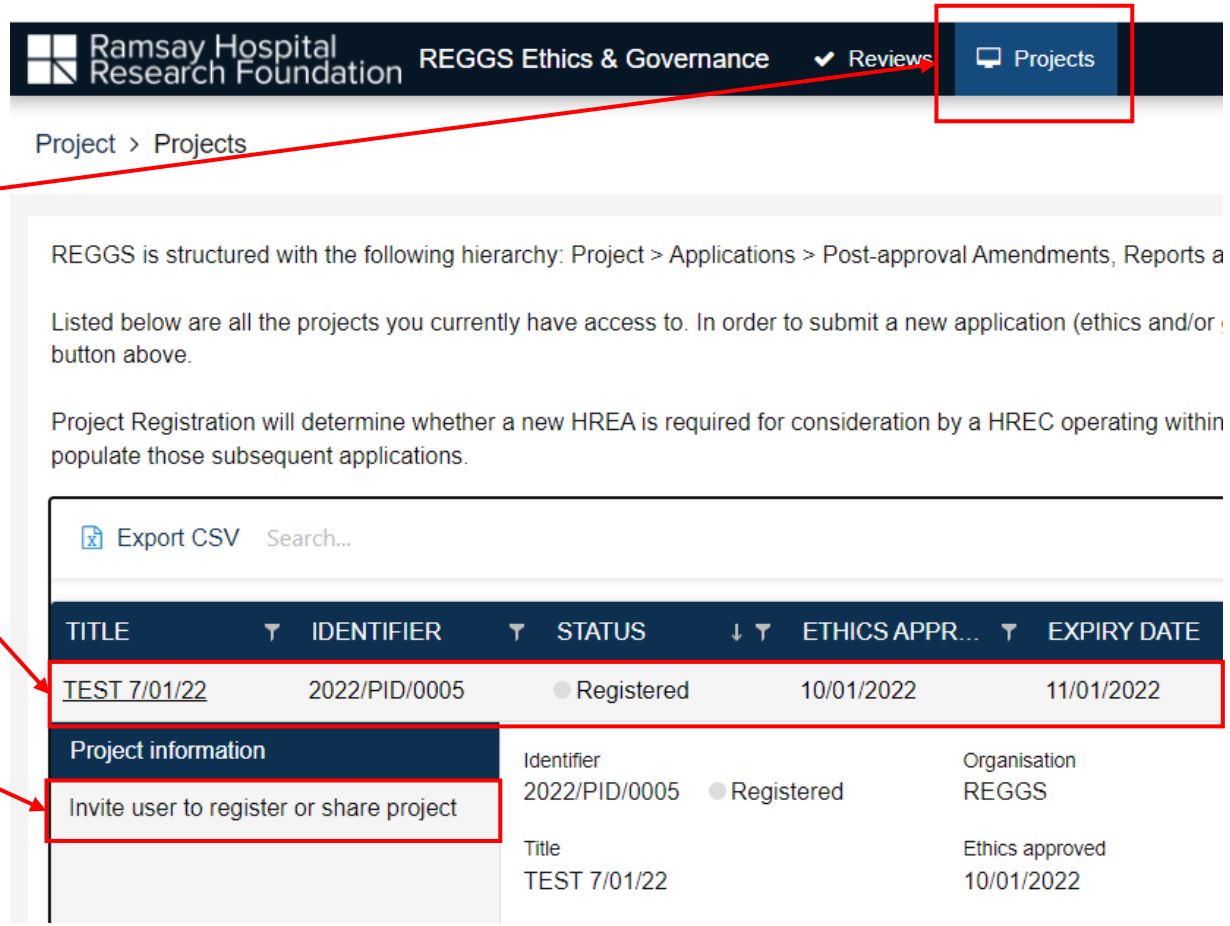
Step 1

- 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”



Instructions continued on next page

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

Ramsay Health Care

How to Share a Project (cont'd)

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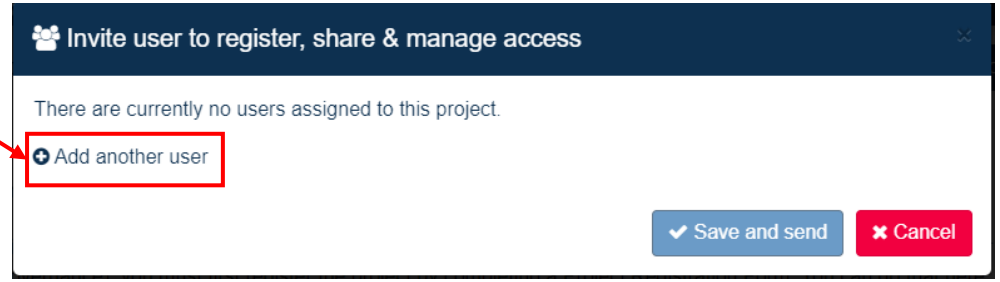
Step 3

- 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"



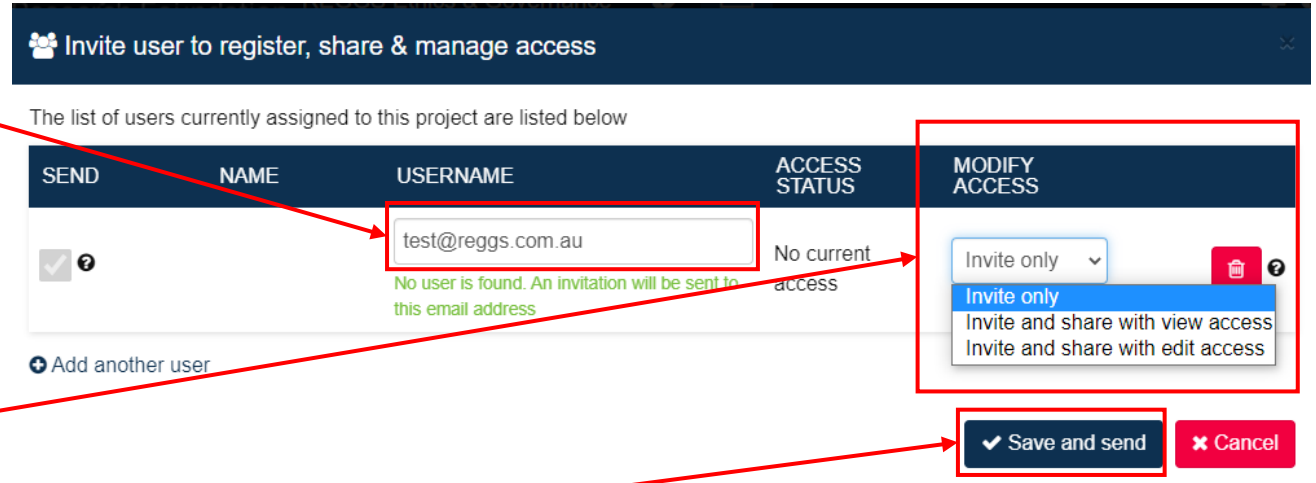
***Note**: In order to view or edit a Project in REGGS, a user must first register for an account.*

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.

Ramsay Health Care

How to Share an Application

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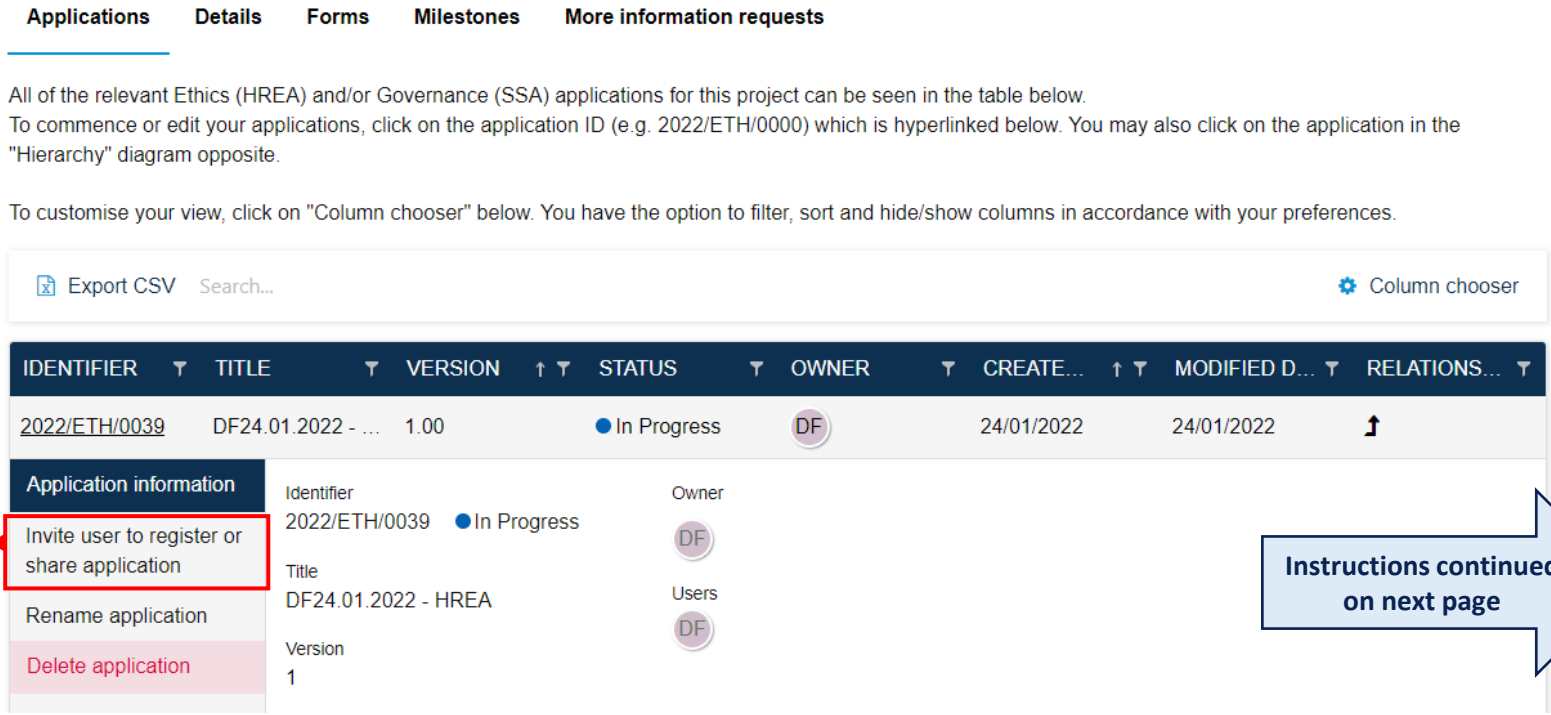
Step 1

- 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”



Instructions continued on next page

Ramsay Health Care

How to Share an Application (cont'd)

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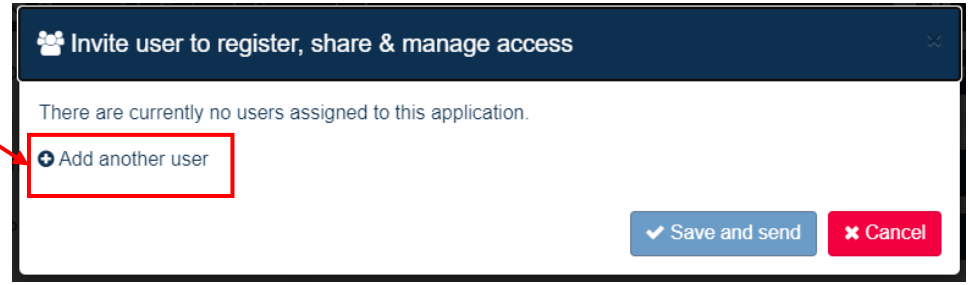
Step 3

- 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"



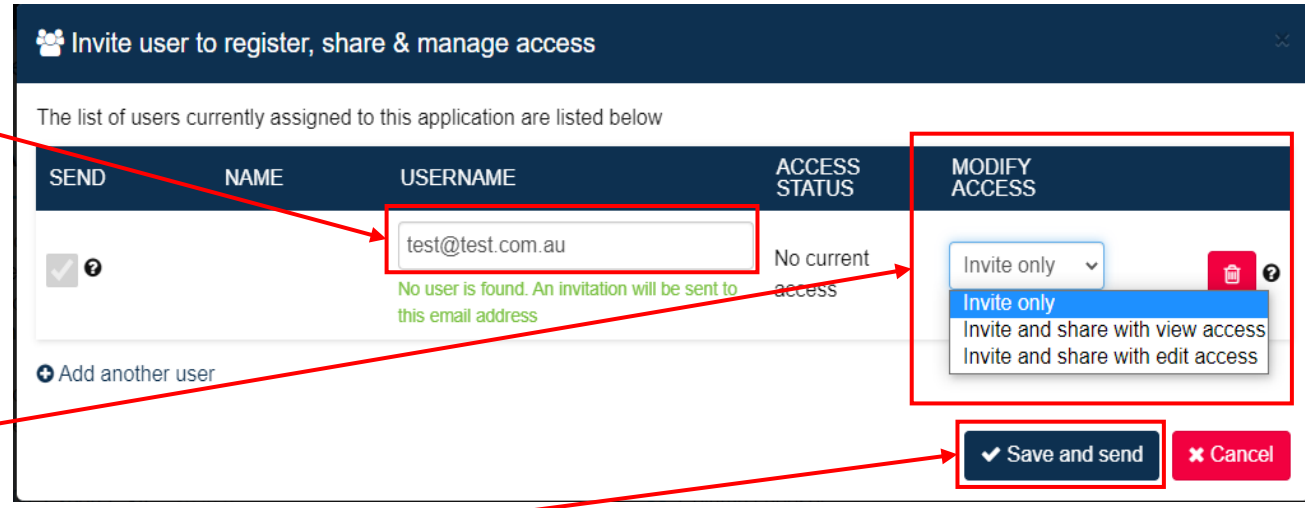
***Note**: In order to view or edit an application in REGGS, a user must first register for an account.*

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.

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How to Submit your Application

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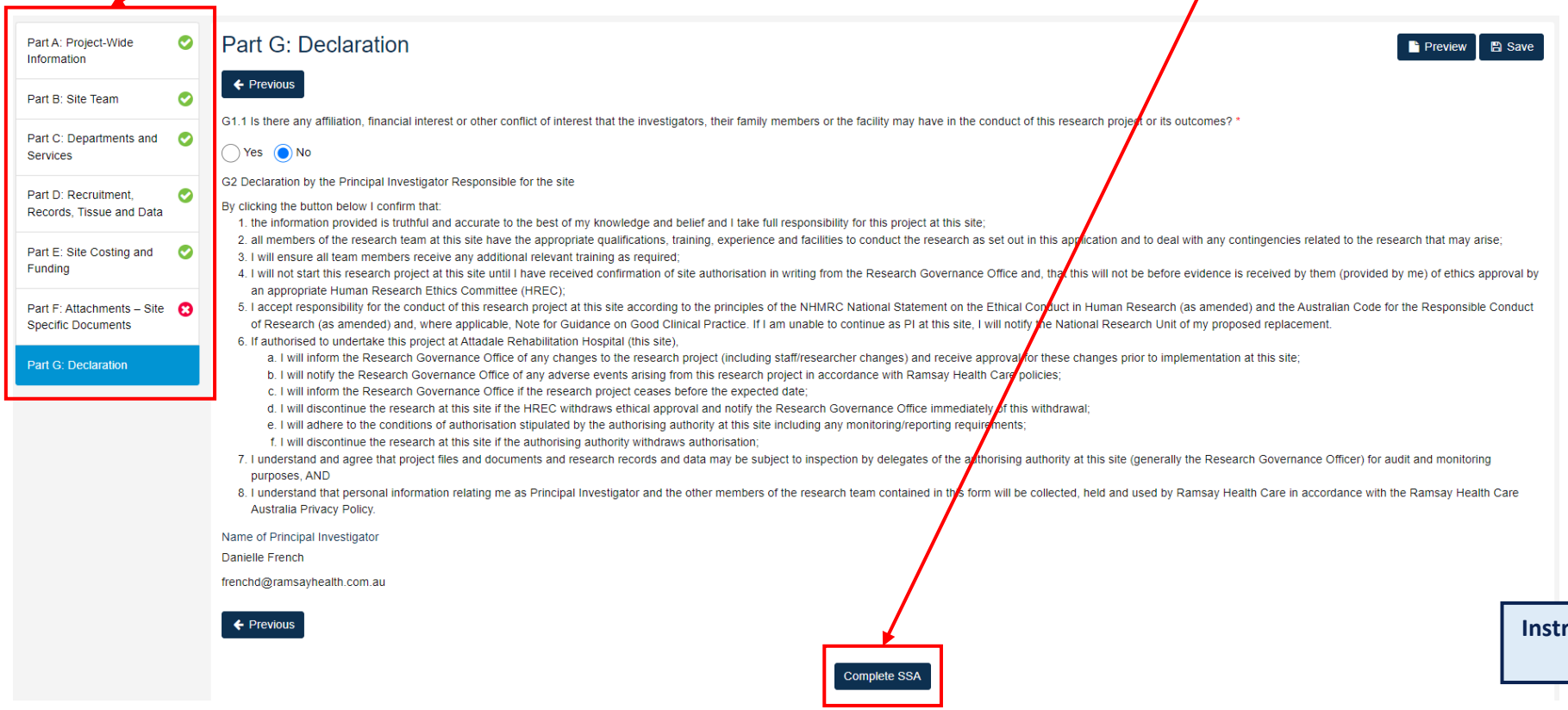
Step 1

- 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 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.***

Instructions continued on next page

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How to Submit your Application (cont'd)

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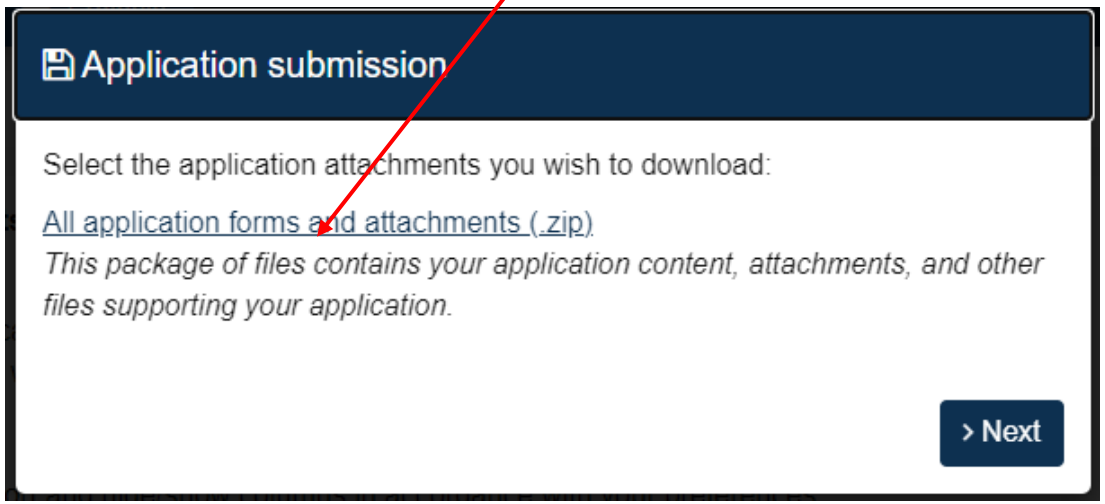
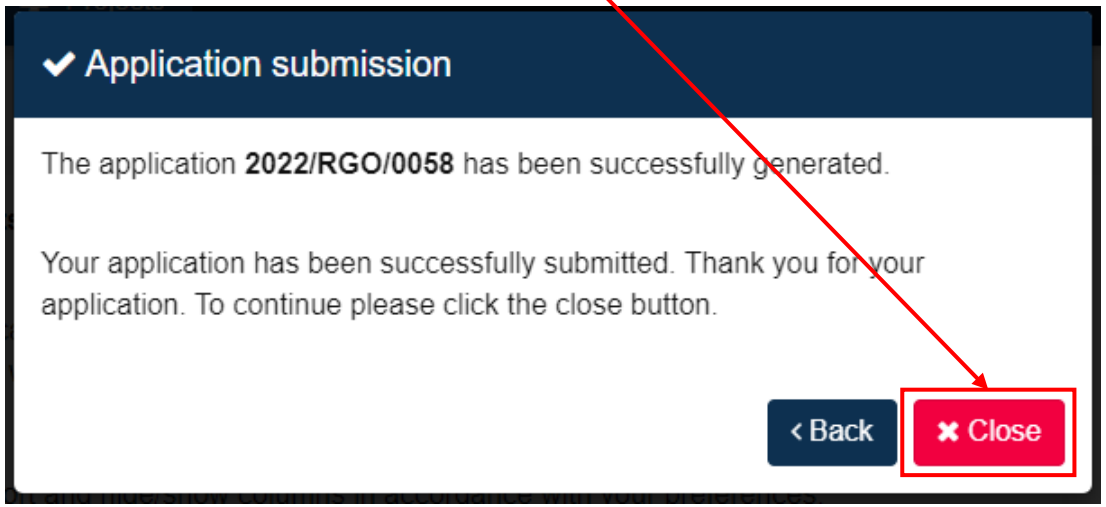
Step 3

- 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.



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

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How to Delete your Application

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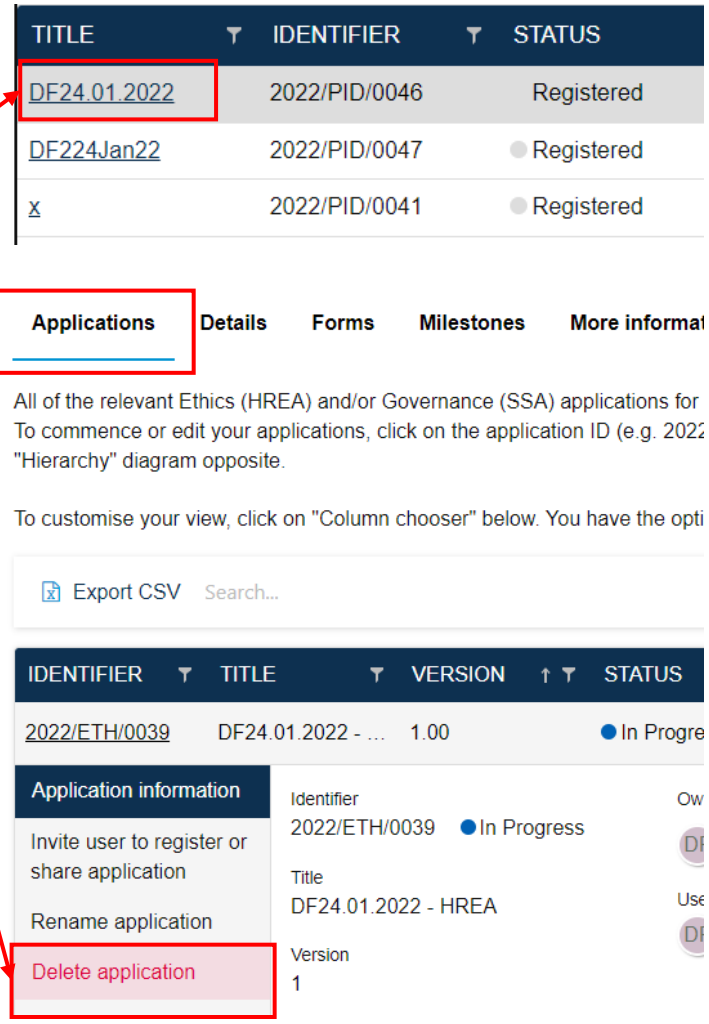
Step 1

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

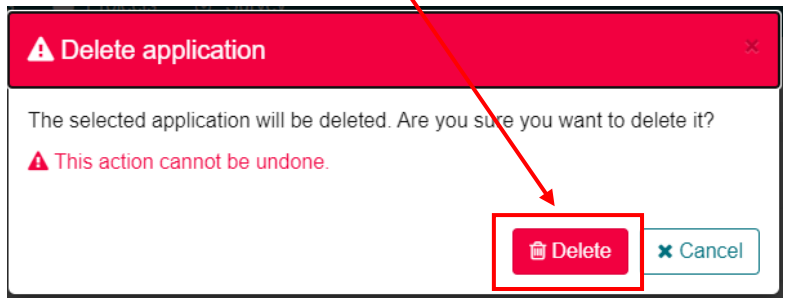
Step 2

- 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"



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.



***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.

Ramsay Health Care

How to delete a draft Project Registration form

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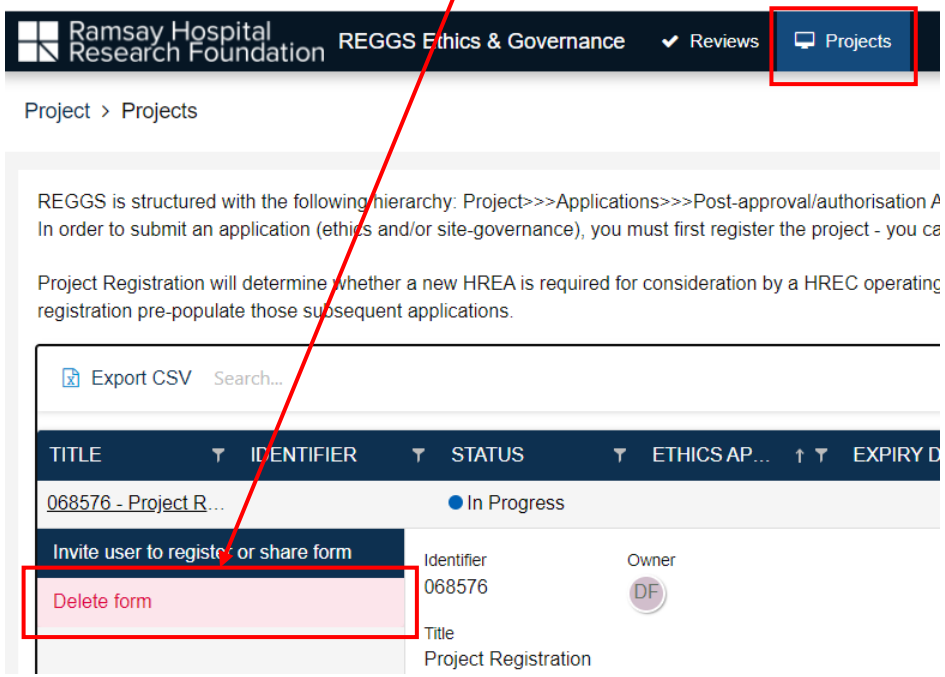
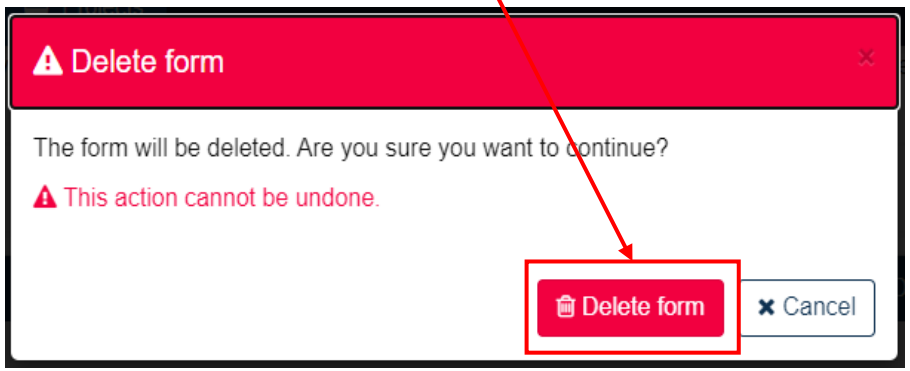
Step 1

- 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.



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”



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

Ramsay Health Care

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

Back to Contents

Step 1

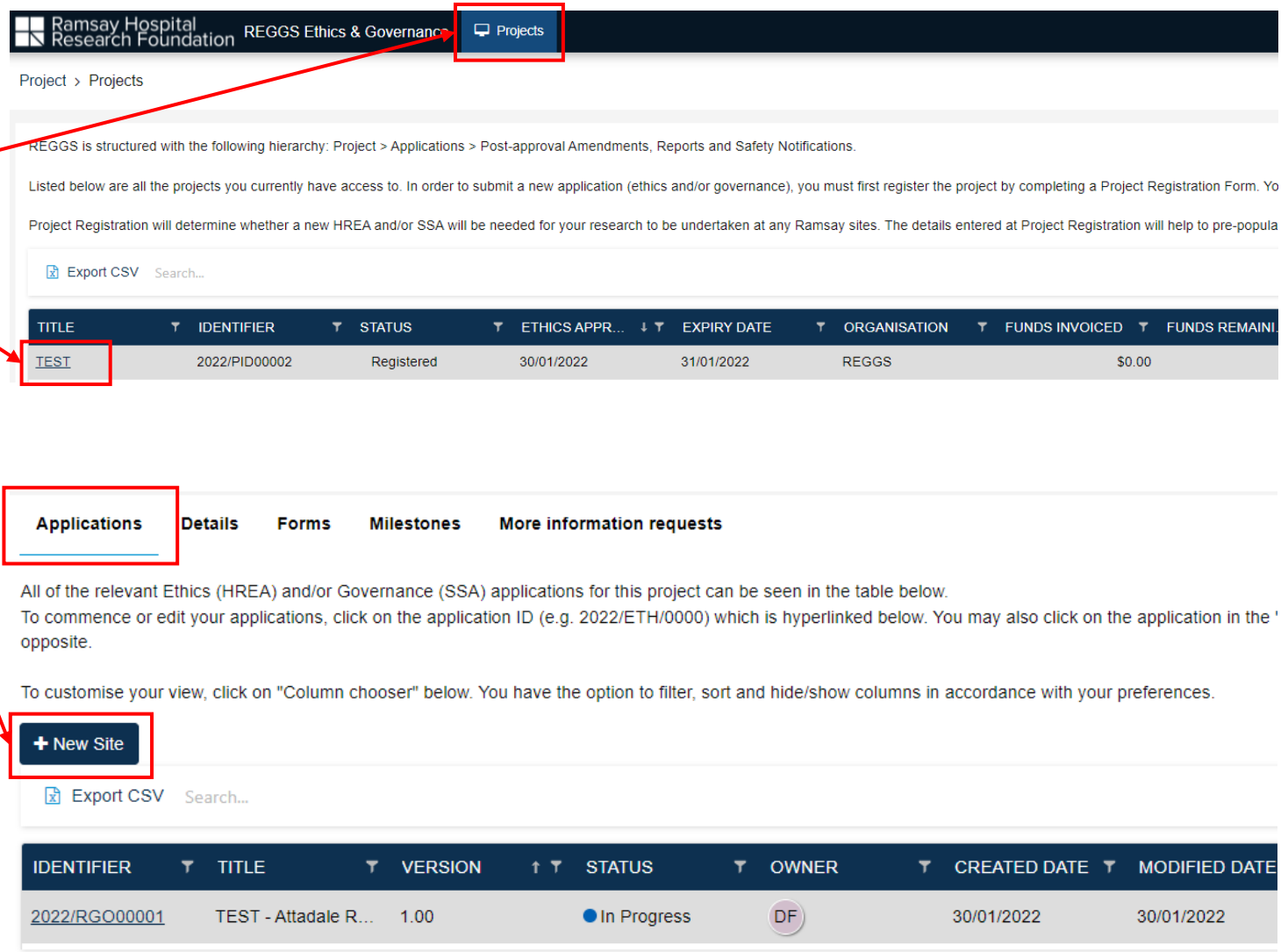
- Click on the Projects tab at the top of the homepage screen.
- Click on the hyperlinked title of your project.

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



Ramsay Health Care

How to submit a Research Governance Amendment

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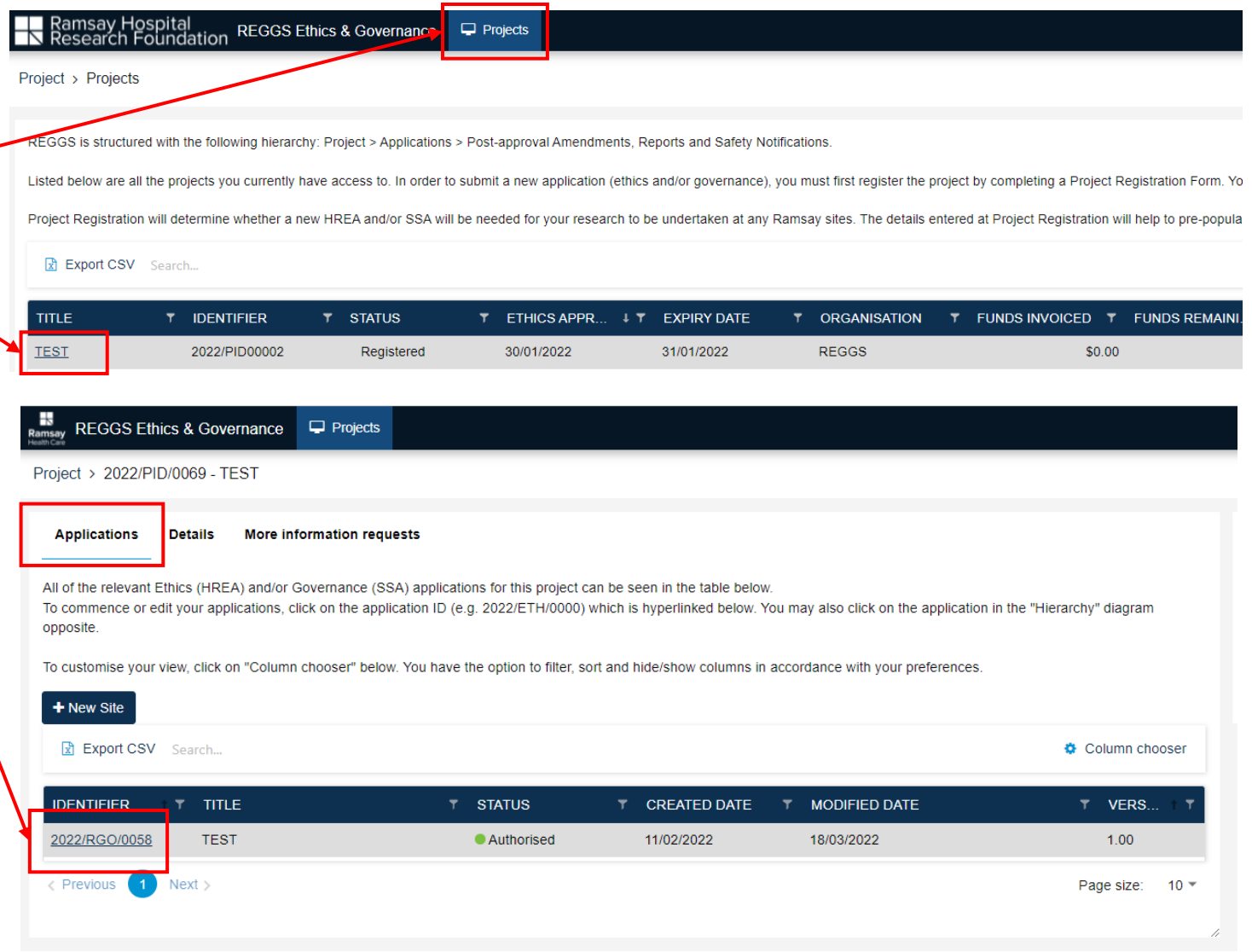
Step 1

- 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



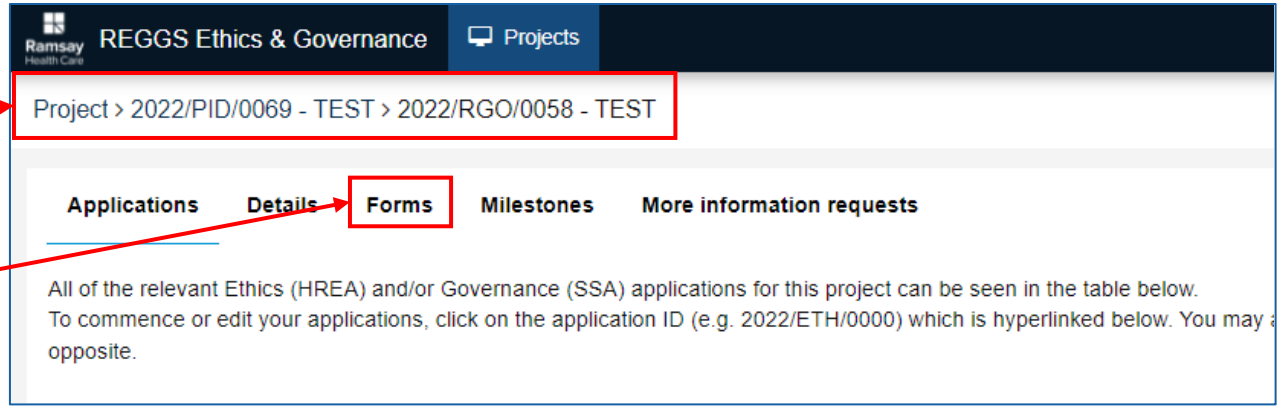
Ramsay Health Care

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

Back to Contents

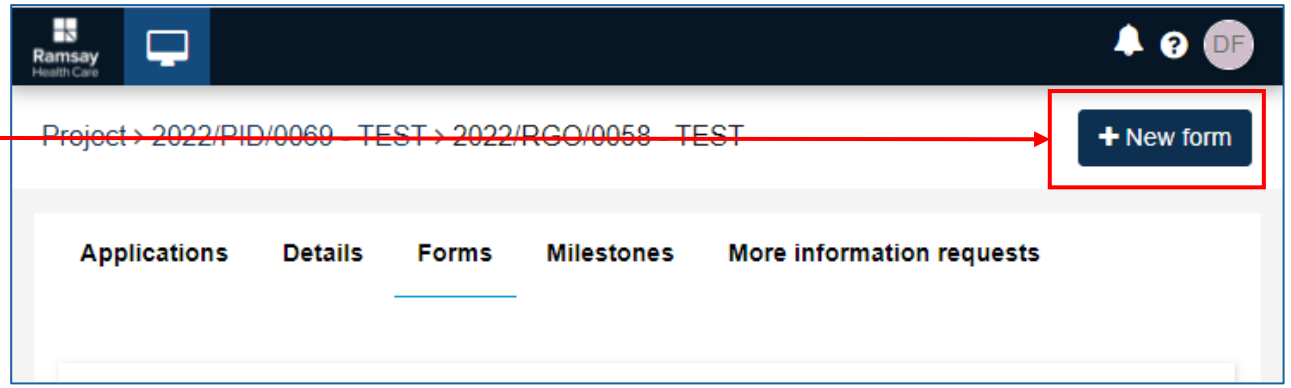
Step 3

- 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



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



Instructions continued on next page

Ramsay Health Care

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

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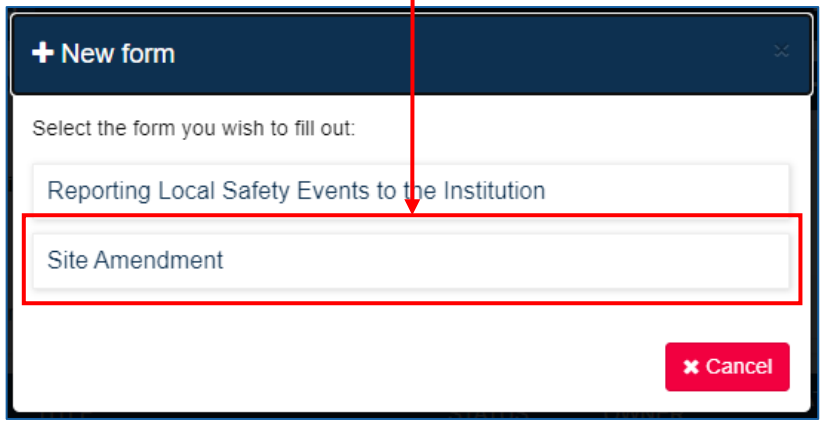
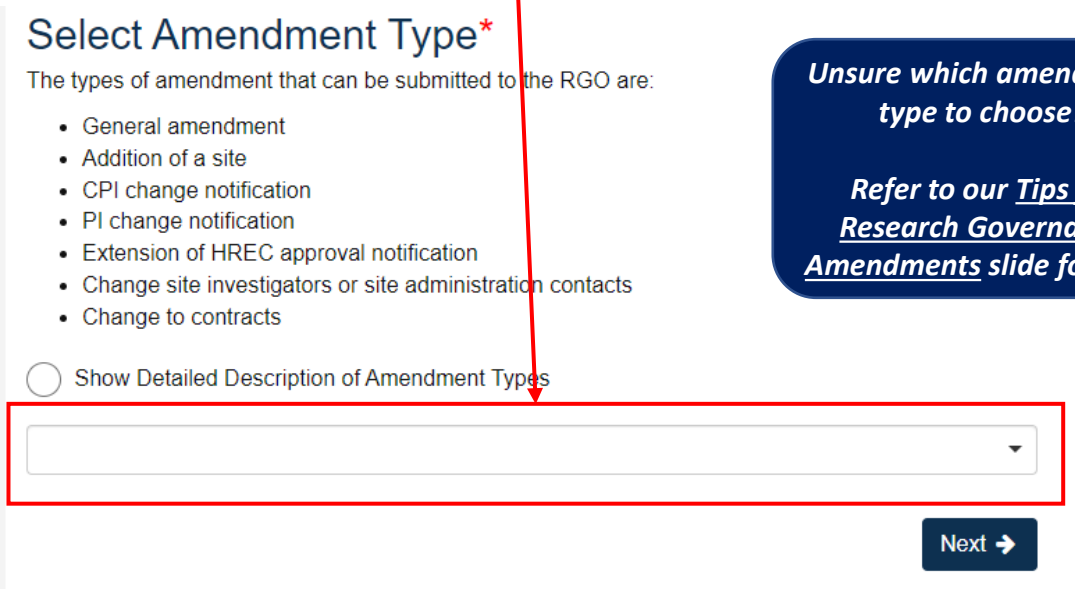
Step 5

- Select "Site Amendment" from the menu



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



Unsure which amendment type to choose?

Refer to our Tips for Research Governance Amendments slide for help

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.*

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Uploading Documents for your Research Governance Amendment

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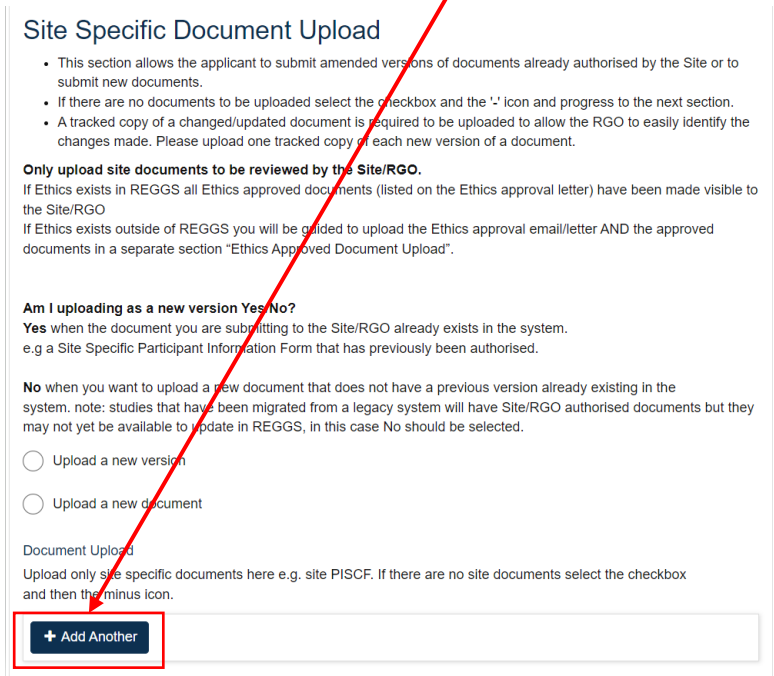
For General Amendments, you have the option to upload study documents in two places:

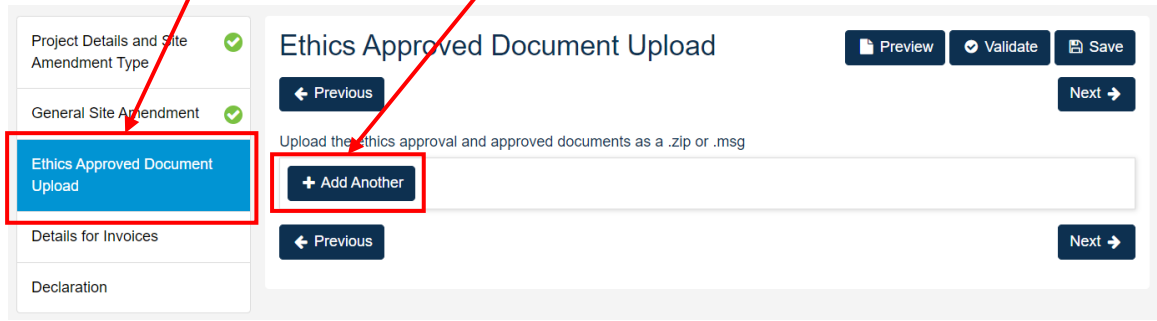
1

- 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.



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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**

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How to submit a Local Safety Report in REGGS

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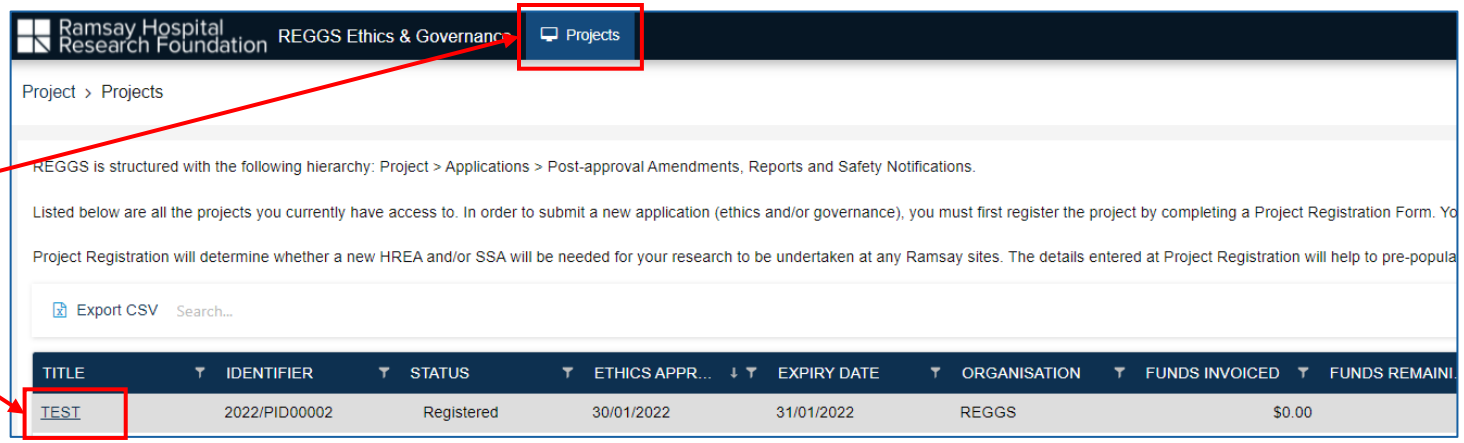
Step 1

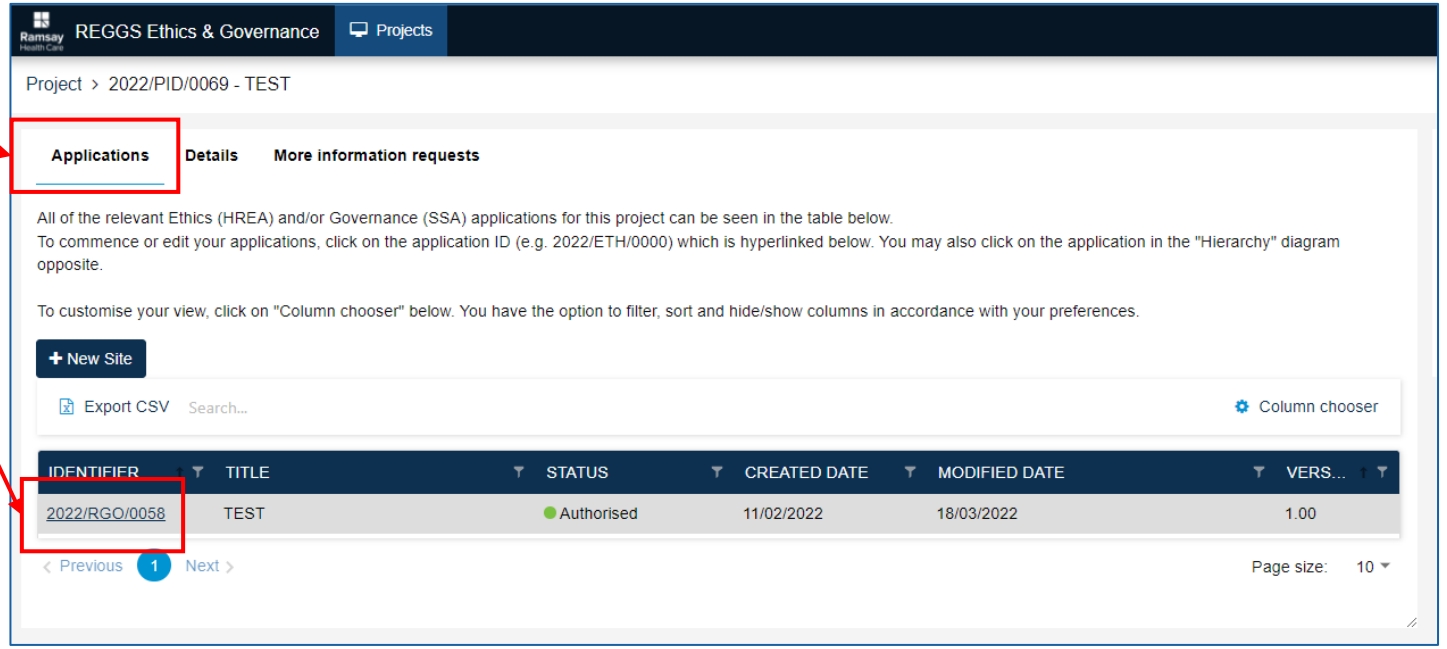
- Click on the Projects tab at the top of the homepage screen.
- Click on the hyperlinked title of your project.



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 Health Care

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

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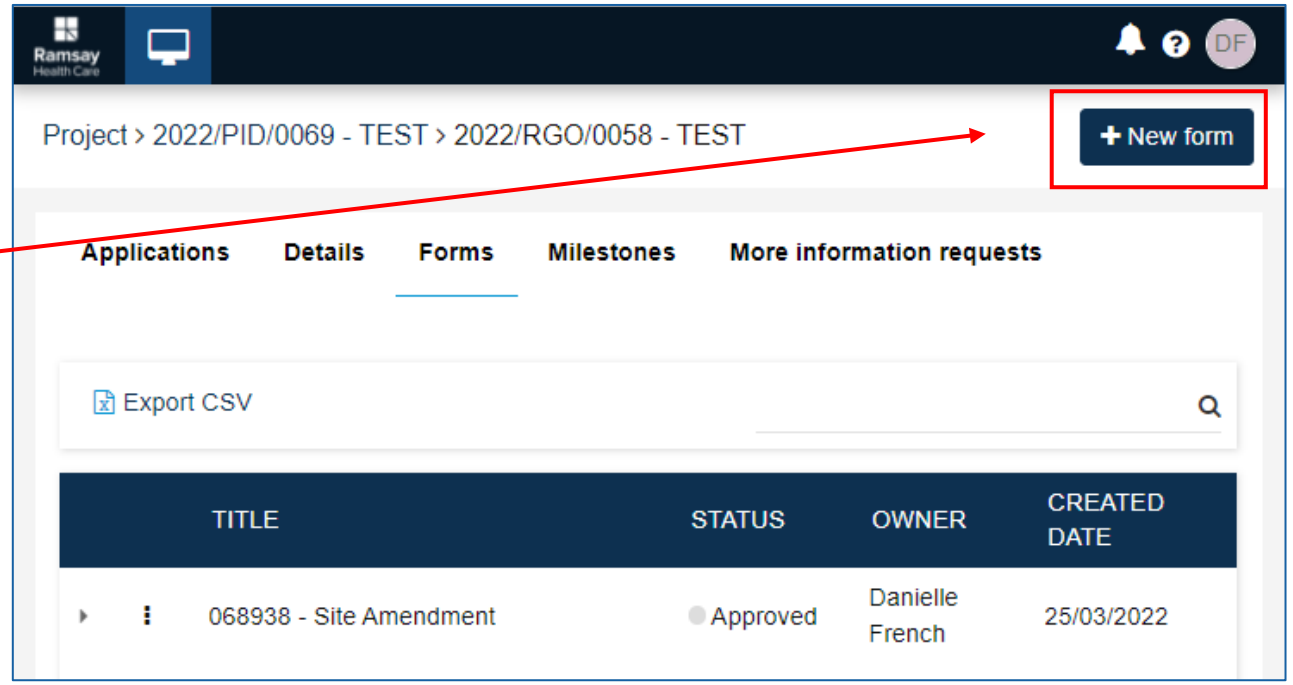
Step 3

- 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

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

Instructions continued on next page



Ramsay Health Care

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

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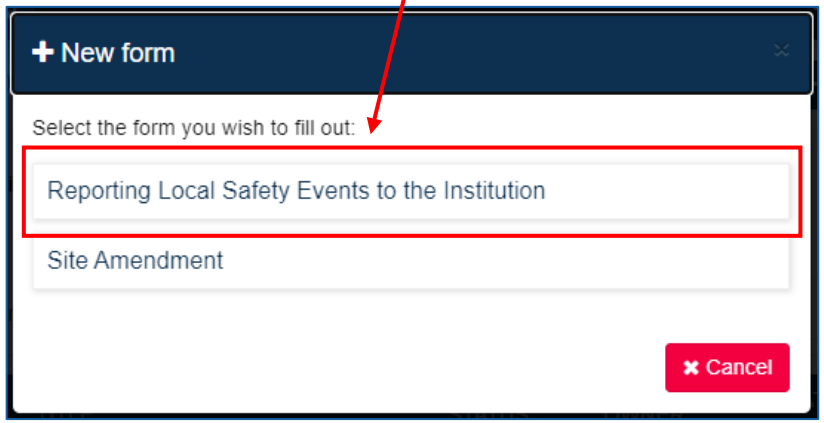
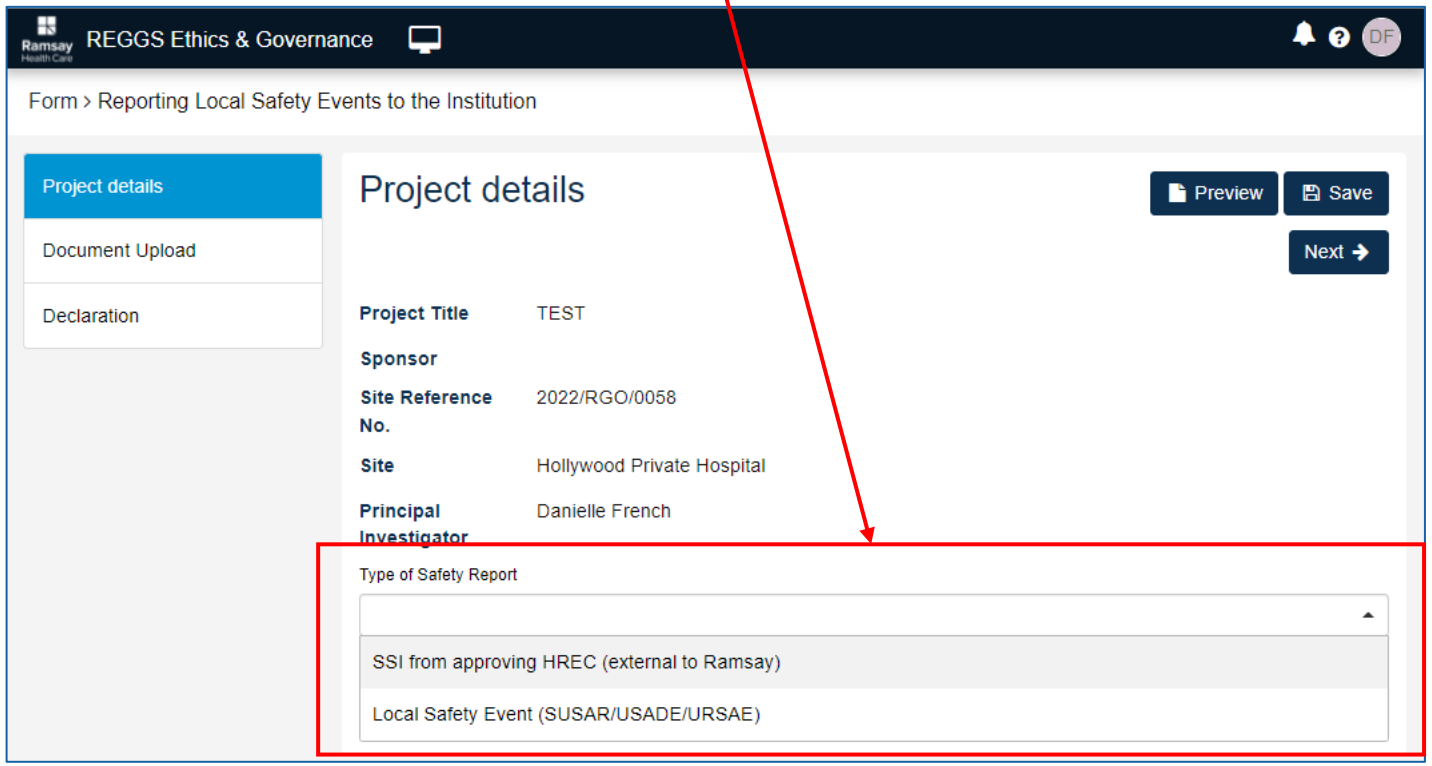
Step 5

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



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

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

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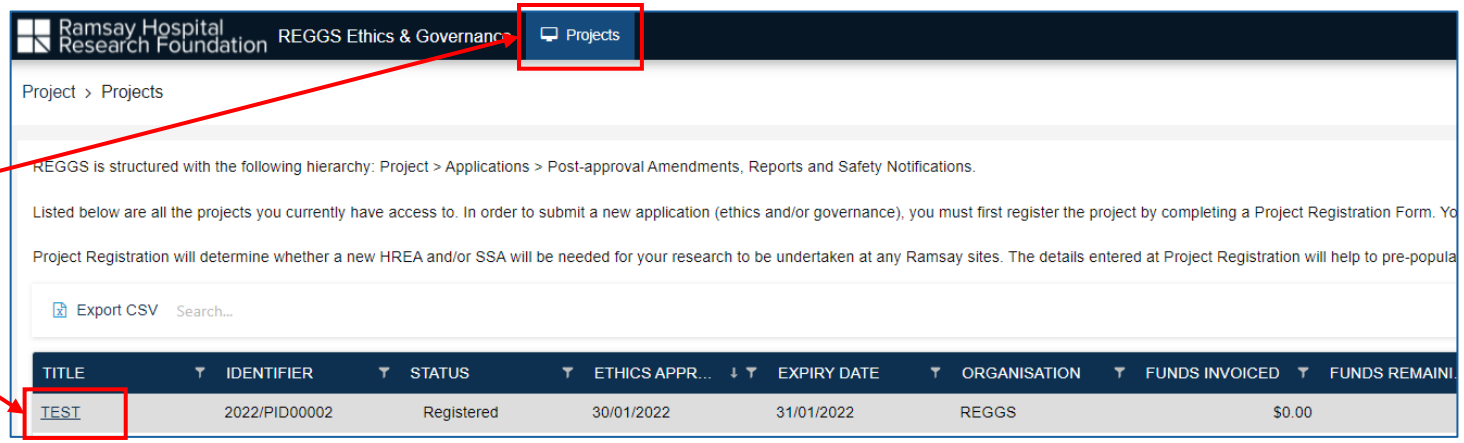
Step 1

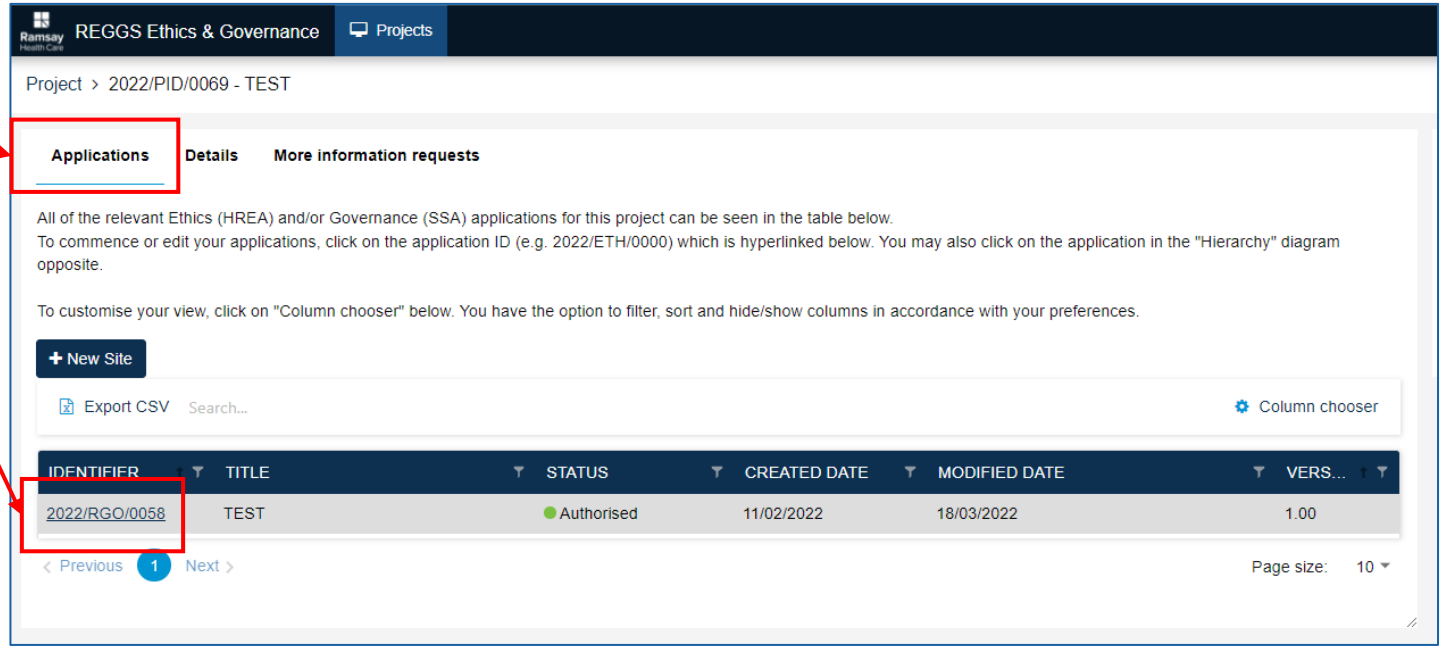
- Click on the Projects tab at the top of the homepage screen.
- Click on the hyperlinked title of your project.



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 Health Care

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

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Step 3

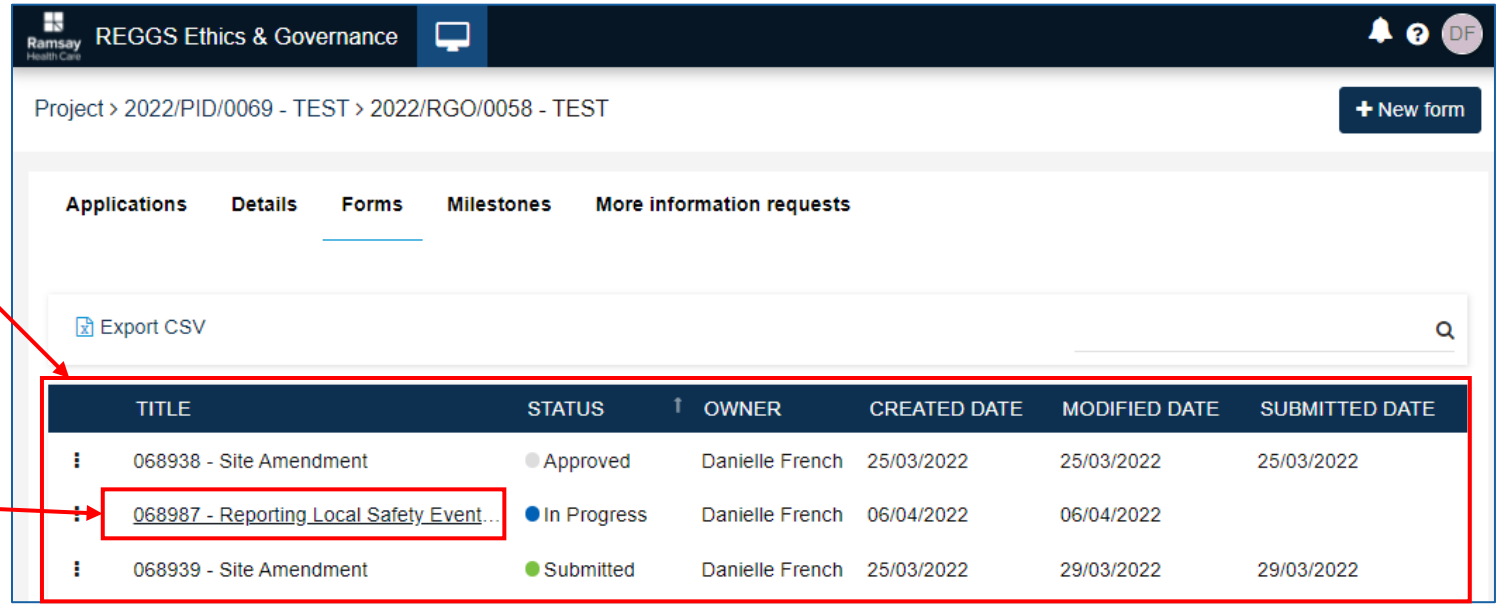
- You will see that the pathway at the top of the screen has updated to include the ID for your selected Application.
- Click on “**Forms**” tab at the top of your screen

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

Step 5

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



Ramsay Health Care

How to download forms and attachments once they are submitted

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Step 1

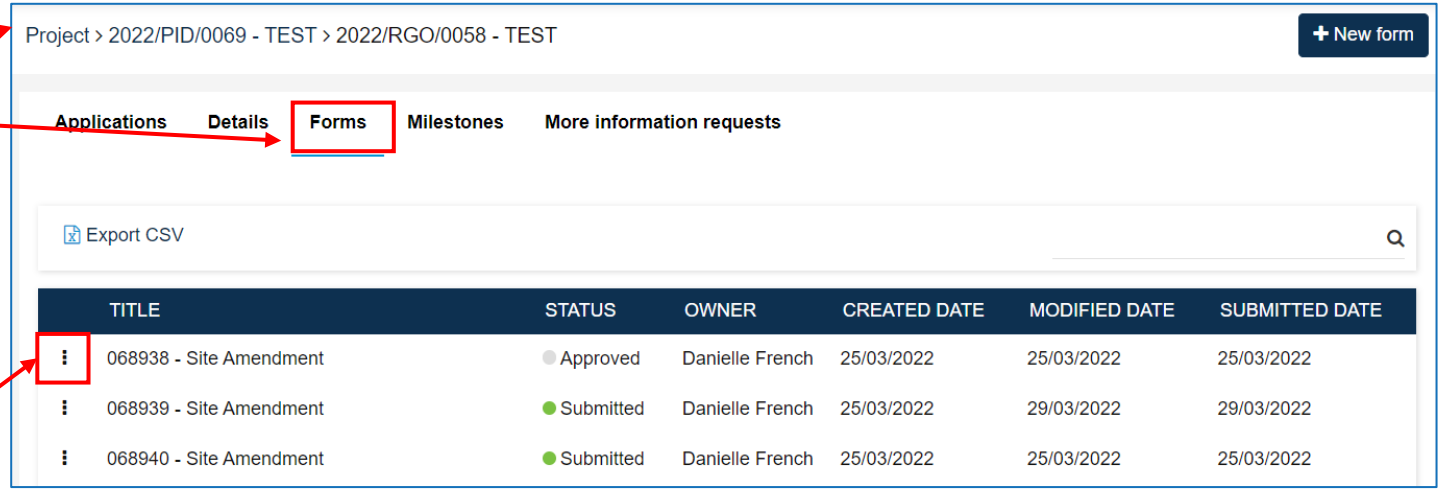
- Locate your approved project
- Click on Forms Tab

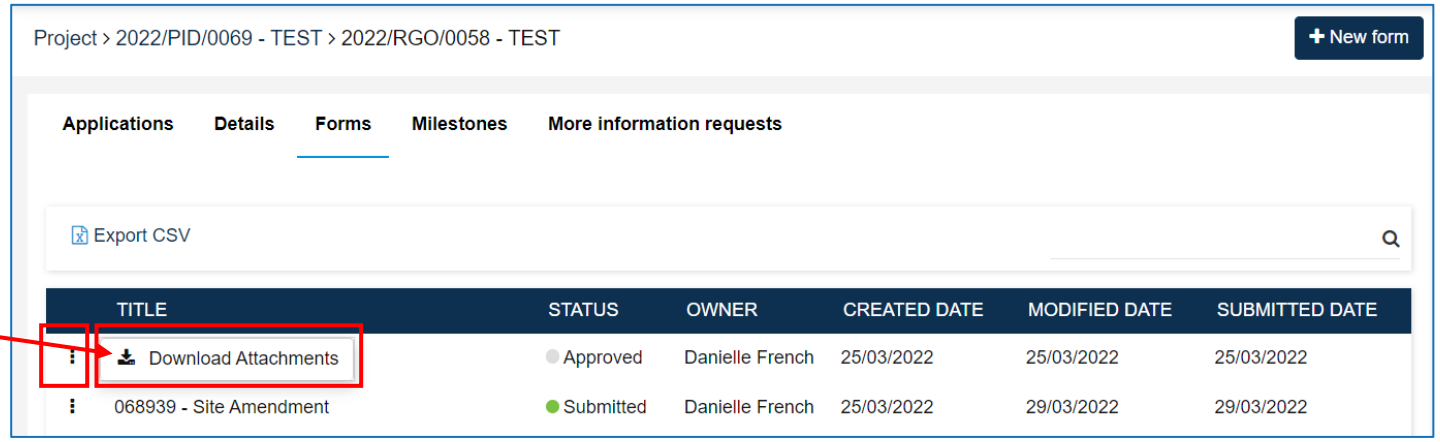
Step 2

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

Step 3

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





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FAQs

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- **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

Ramsay Health Care