Frequently Asked Questions (FAQs) relating to Annual Progress Report Submission

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If you're unable to resolve your question, please contact the SAGE Admin Team for assistance.

Who is responsible for submitting the report forms?

There are two types of Progress Reports to ensure continuous monitoring of research projects involving human participants:

1. **HREC Annual Report** – The **Sponsor** is responsible for submitting the HREC Annual Report for <u>commercially sponsored studies</u>, while the **CPI** is responsible for submitting the report for <u>non-commercial studies</u>, such as investigator-initiated and collaborative research group studies. This report aims to track ethical compliance, participant safety, and adherence to the approved research protocol across ALL SITES in Australia.
2. **RGO Progress Report** – **The Site PI** is responsible for submitting the RGO Progress Report. This report addresses site-specific governance aspects, including accountability, investigator delegation, and other institutional metrics within a St Vincent's site or its satellite sites.

Report type	Responsible party	Focus of report metrics
HREC Annual Report (managed under SVH Project on SAGE)	• **Sponsor** for commercially-sponsored studies; • **CPI** for non-commercial study (Investigator-initiated and collaborative research group research).	Track ethical compliance, participant safety, and adherence to the approved research protocol across ALL SITES in Australia.
RGO Annual Report (managed under SSA Project on SAGE)	The **Site PI** is responsible to submit the RGO Report.	To monitor site-specific governance aspects, including accountability, investigator delegation, and other institutional metrics within a St Vincent's site or its satellite sites.

SVH = St Vincent's HREC ; SSA = Site-Specific Assessment

What are the different types of reports, and which one should I submit?

There are two types of reports, and the required form submission depends on **SVHM's involvement in the study,** for example:

1. Is St Vincent's Melbourne the reviewing HREC and/or a participating site?
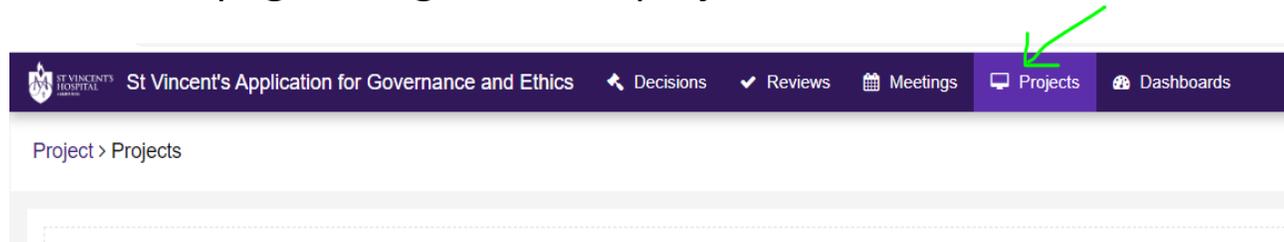2. Is the study multisite or single-site?

Refer to the table below:
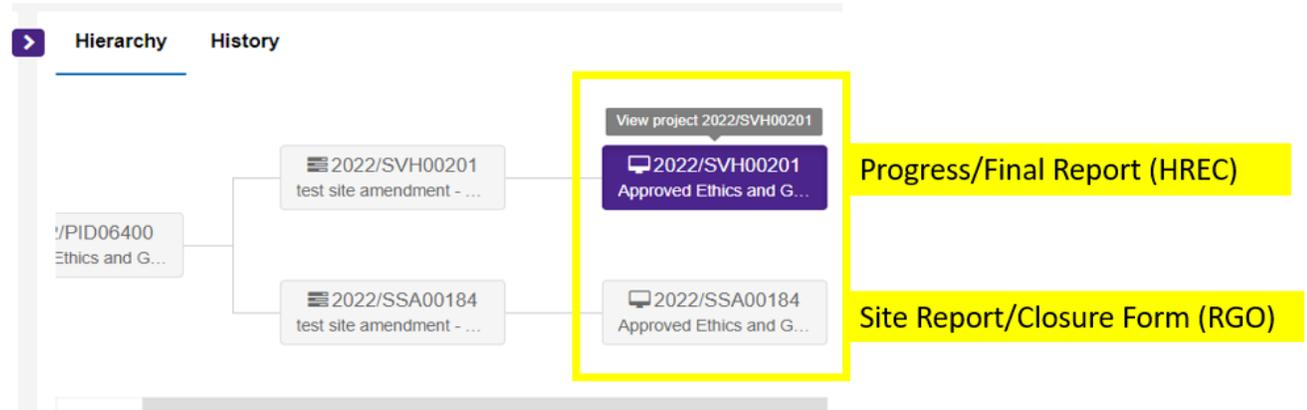
SVH = St Vincent's HREC ; SSA = Site-Specific Assessment

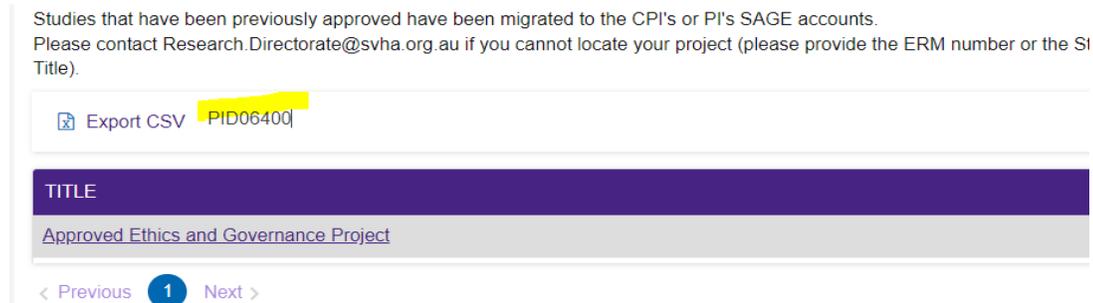| Project types	SVHM's involvement in the study	Report form required
Ethics (SVH) only project	SVHM is the reviewing HREC; SVHM is not participating as a site	Progress/Final Report (HREC)
Governance (SSA) only project	SVHM is participating as a site; study is reviewed by an external HREC	Site Report/Closure Form (RGO)
Both SVH and SSA project (Single-site)	SVHM is both the HREC and the ONLY participating site	Site Report/Closure Form (RGO)
Both SVH and SSA project (Multi-site)	SVHM is both the HREC and is one of the participating sites for a multisite study in Australia	BOTH forms

Where can I find the report form?

1. From the homepage, navigate to the project tab.

St Vincent's Application for Governance and Ethics   Decisions   Reviews   Meetings   Projects   Dashboards

Project > Projects

2. Type in the PID or title of the project on the Search Bar.

Studies that have been previously approved have been migrated to the CPI's or PI's SAGE accounts.
Please contact Research.Directorate@svha.org.au if you cannot locate your project (please provide the ERM number or the St Title).

Export CSV   PID06400

TITLE

Approved Ethics and Governance Project

‹ Previous   1   Next ›

Continue with Step 3 and 4 in the next page…

Contact Research.directorate@svha.org.au if you cannot find a project.

Where can I find the report form? – *cont.*

3. Under the Hierarchy

- Select the SVH project to submit Progress/Final Report (HREC); or

- Select the SSA project to submit Site Report/Closure Form (RGO).
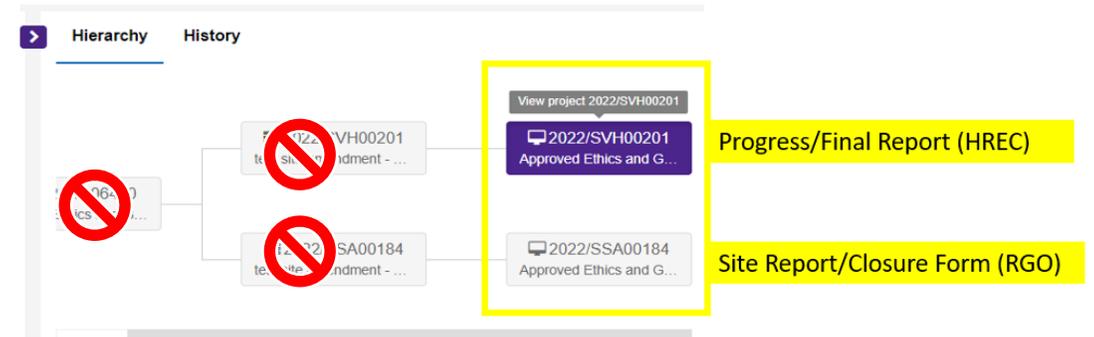
4. Navigate to the 'Milestones' tab of the project.
You will see a report listed here.

If you are unsure which report you need to submit, please refer to the table on types of progress reports.

Why can't I see the report form?

- If you have followed the steps on Pages 3–4 but cannot find the form, it is likely located within the corresponding project under the **Hierarchy**.

- For example, if you initially searched in the **SVH project**, try checking the **SSA project** under the **Hierarchy** tab, or vice versa.
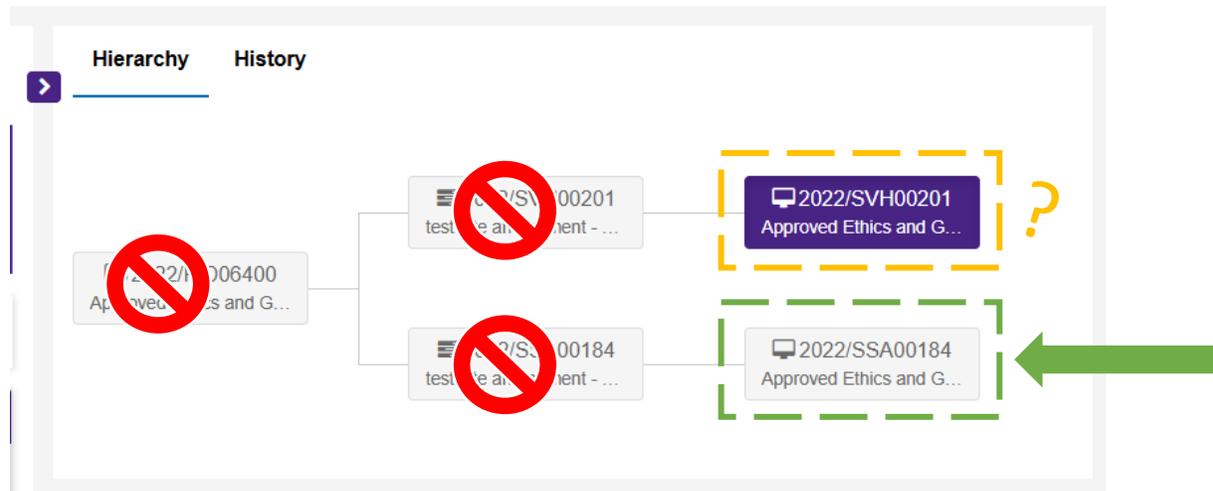
Still having issue?
Contact Research.directorate@svha.org.au if you are unable to find the form in any projects.

How do I submit a Final Report instead of Progress Report?

Depending on the study status, a progress report or a completion report will be generated automatically. This is managed within the report form.

Reporting Level	Study Status	Type of report generated
Project Report (HREC Form) – overall project across all sites managed under the SVH project	• Not Yet Commenced • In Progress	An Annual Progress Report will be generated under the Project Milestone. Submit report on 1 May each year until project completion.
	• Closed (post-analysis) • Abandoned • Terminated	A Project Final Report will be generated under the Project Milestone. Submit anytime.
Site Report (RGO Form) – governance level at any SVHM site managed under the SSA project	• Not Yet Commenced • Continuing	An Annual Progress Report will be generated under the Project Milestone. Submit report on 1 May each year until project completion.
	• Completed • Abandoned	A Site Closure Report will be generated under the Project Milestone. Submit anytime.
External Site Closure Form – closure of one of the sites for a multisite study	Use this form if only any non-SVHM site is closed, abandoned or terminated. Overall study is still in progress across all other sites.	An External Site Closure Form can be submitted anytime.

Please refer to the status definitions on the following pages.

Progress or Final Report – Study statuses within the HREC Form

Study Status

◯ Click here for Progress Report Status definitions

Study Status *
Closed (post analysis)   × ▼

ⓘ Based on your above response, a Project **Final Report** will be generated and submitted at the completion of this form.

Selecting one of these statuses will generate an **HREC Progress Report**, indicating that the study is ongoing at one or more participating sites and that a future report is expected:

- **Not Yet Commenced:** No clinical activities (including recruitment) have started.

- **In Progress:** Clinical or study activities have commenced. Data collection may have completed, but data analysis is still ongoing, follow-up visits may occur.

Selecting one of these statuses will generate an **HREC Final Report**, indicating that the study has been _completed across all participating sites_ and that no future reports will be submitted for this project:

- **Closed (post analysis) –** The study has finished normally; participants are no longer being treated or examined. The database is locked, and data analysis is complete.

- **Abandoned –** The application was approved/authorised, but the project will never commence.

- **Terminated –** The study started but was discontinued by the investigator or sponsor before study completion. Activity will not resume. Possible reasons include ethical, safety, financial, or other grounds. This study will never progress to "Closed (post analysis)".

Progress or Final Report – Study statuses within the RGO Form

Site Progress

◯ Click here for Progress Report Status definitions

Study status

Completed

ⓘ Based on your above response, a **Site Closure Report Form (RGO)** will be generated and submitted at the completion of this form.

Selecting one of these statuses will generate a **Site Progress Report**, indicating that the study is ongoing at the site and that a future report is expected:
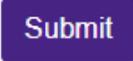
- **Not Yet Commenced** - No clinical activities involving participants (including recruitment) have started.
- **Continuing** – Clinical or study activities have commenced.

Selecting one of these statuses will create a **Site Closure Report** - study has completed no future reports will be submitted:

- **Completed**: Completion of a study or data analysis at this site.
- **Abandoned**: The application has been approved/authorised, but it has been determined that the project will never commence.

Why can't I submit the form?

Project Details	✅
Progress Summary	✅
Recruitment/Data/Samples	✅
Document Upload	✅
Declaration	✅

- Review the form to ensure all responses are correctly entered. Some fields are mandatory and must be completed. A green tick will appear next to each page once the mandatory fields are answered.

- As many projects were migrated, some information may still be outdated. If you notice any incorrect details, please contact research.directorate@svha.org.au.

- When you're ready to submit, click the **Submit** button on the final page (Declaration page).

- If you are unable to see the Submit button, it may be due to one of the following reasons:

  1. **The submission period for report forms has not yet opened.** Starting in 2025, all Annual Progress Reports cannot be submitted before 1 May. If you attempt to submit a progress report form before this date, the Submit button will be disabled. Please wait until 1 May to submit the report. See Change to Annual Progress Report Submission Period 2025 for more details.

  2. **You have not been listed as the correct user to submit the form.**
     For the HREC Report, only the listed CPI or Sponsor can submit the form;
     For the RGO Report, only the PI can submit the report.

Any changes to the CPI or PI must be approved through an amendment request. If you have received approval for a new CPI/PI and the record on SAGE is outdated, please email research.directorate@svha.org.au to update the record. Similarly, please contact us via email to update the Sponsor contact.

How do I download a previously submitted report?

A PDF copy of the live version of the form can be downloaded by clicking the **Preview** button in the top right corner of the page. Please note, the date of submission will always appear as *today's date*.

If you intend to download **a previously submitted report**, please refer to these steps

Step 1
Navigate to the Milestones tab to locate and select the report of interest.

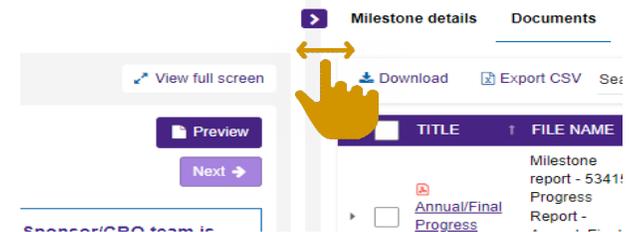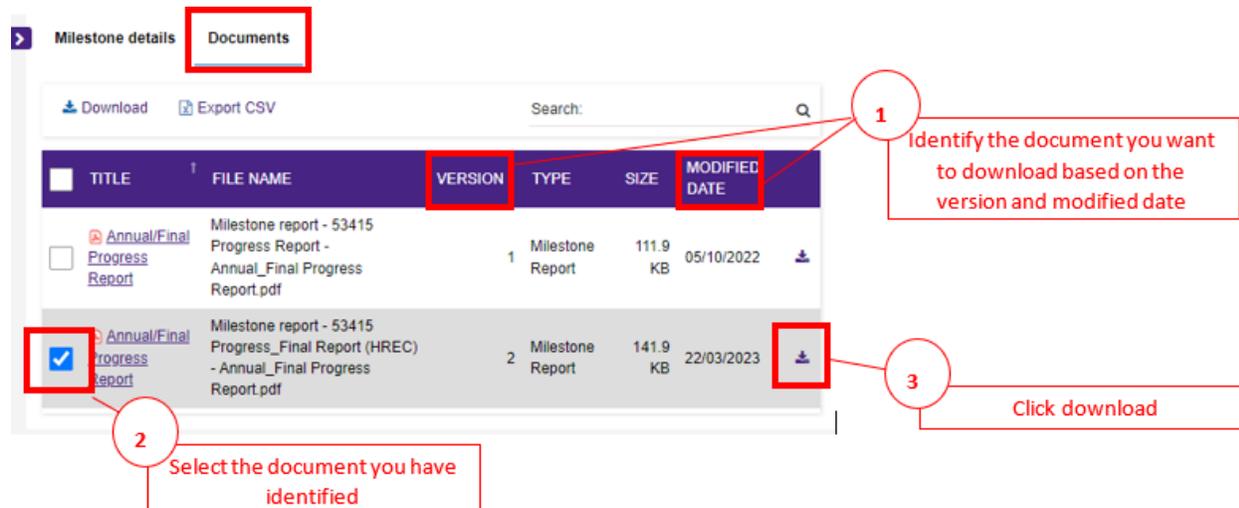# How do I download a previously submitted report? – *cont.*

Step 2
You may refer to the data entered in this report form.
You can also find the option to download the PDF copy in the menu on the right – click on this arrow button to expand the menu.

Tip: If you can't see the full table, you can expand its size by hovering your cursor between the form and the table border.

Step 3
Under the **Documents** tab, you can see a list of submitted report.

1. Identify the document you want to download based on the version and modified date
2. Select the document you have identified
3. Click download

What happens after the report submission?

- The Status of the form will change from 'Pending' to 'Received'

IDENTIFIER	MILESTONE TITLE	DETAIL	ORGANISATION	STATUS	DAYS REMAINING ↑	DUE DATE
2022/SVH00201	📄 Progress/Final Report (HREC)	Progress Report	SVHM	● Received	39 days	1/05/2023

- You will receive an email notification that the report has been submitted

Wed 22/03/2023 2:45 PM
admin@svha.org.au
2022/SVH00201: 01/05/2023 - Progress/Final Report (HREC) Submitted

- The report will be reviewed by the RGU. There will be two outcomes of the report:

Outcomes	Description	Next steps
Report status change to "Achieved"	You will receive an email stating that this annual report has been acknowledged; no further action is required.	If the study is continuing, you will need to submit another report next year. If the study is closed, the project status will change to 'Completed', no further report will be required.
Report status change to "Revision"	If there are any follow-up questions, you will receive an email from **admin@svha.org.au** outlining queries regarding your report.	Please refer to the next page for steps on submitting a revision or response to the report query email.

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Progress report – Responding to query

Refer to Pages 3–5 to locate your report. You should be able to find the Milestone Report under the "Revision" status.

IDENTIFIER	MILESTONE TITLE ↓	DETAIL	ORGANISATION	STATUS	DAYS REMAINING	DUE DATE
2022/SVH00201	📄 test final report		SVHM	🟡 Revision	⚪ 22 days	7/05/2023

Project Details ✅

Progress Summary ✅

Recruitment/Data/Samples ✅

Document Upload ✅

Revision to Annual Report Form ❌

Step 1
Remember to update the response to
"**Is this a revision of the Annual Report Form**?"
on the first page of the form to "**Yes**."

Is this a revision of the annual report form as part of a query? *
◉ Yes
◯ No

ℹ Please revise the form or provide your comment on the final page.

Step 2
Revise the report as needed. You do not need to re-enter your responses in the form.

Step 3 (in the final page)
- You may provide your response to the RGU queries.
- Tick the **declaration checkbox**.

Please provide your comment to the query below.

◉ By submitting this revision, I confirm the following:

- The information provided in this report is complete and correct.
- The project is being conducted in keeping with the conditions of approval of the reviewing HREC (and subject to any changes subsequently approved).
- The project is being conducted in accordance with the protocol.
- Any significant protocol deviation or violation has been reported to the reviewing HREC.
- The project is being conducted in compliance with the National Statement on Ethical Conduct in Human Research (NHMRC, 2007) and Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (NHMRC, 2016), or as amended.

- **Submit** the report form. If the ▪Submit▪ button is not visible, please make sure you have completed Step 1 (update "Is this a revision of the Annual Report Form" to "Yes").

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Sharing the project with other users

Important Note: You may share the project with other users to assist in completing the report. However, only users with the assigned role can submit the form.

- For the HREC Report, only the listed CPI or Sponsor can submit the form;
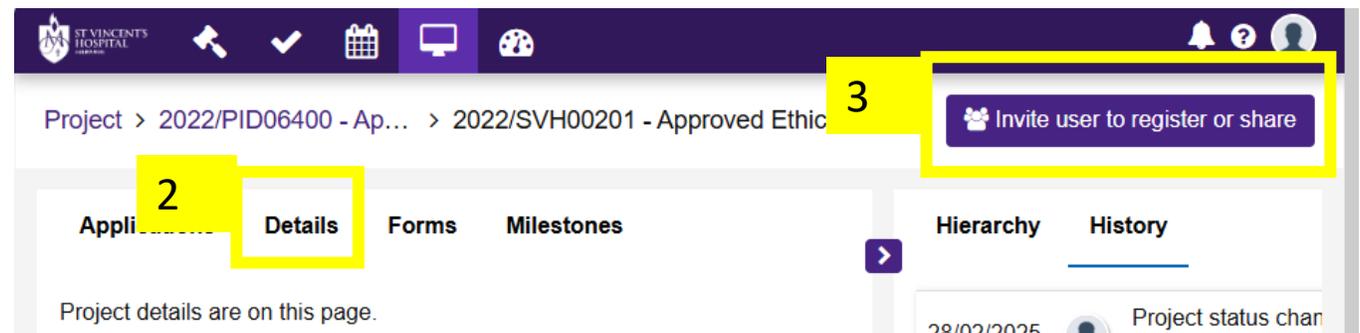
- For the RGO Report, only the PI can submit the report.

If you need to update the contact role, please email research.directorate@svha.org.au.
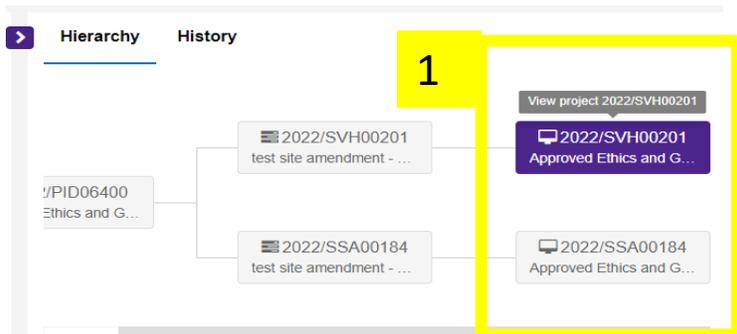
Step 1: Locate the project ([See steps 1-3 from page 3-4](#))

Step 2: Navigate to the '**Details**' tab, not the '**Milestones**' tab in the project page.

Step 3: Click the '**Invite user to register or share**' button

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Sharing the project with other users – *cont.*

Step 4: Click "**Add another user**"

Step 5: In the Username field, enter the person's email address to look up their SAGE account

Step 6: Select "**Share with Edit Access**"

Step 7: Click '**Save and Send**'. This will save the access and notify the recipient via email that the project has been shared with them.

If the person does not have a SAGE account, the message above will appear. Select "**Invite and share with edit access**" and hit "**Save and send**". The person will receive an invitation email to register a SAGE account to access the project. See how to create a SAGE account in the next page. Once the person has registered a new account, they will have access to the project you share with them.

How do I create a SAGE account?

- Register a new account on https://research.svhm.org.au/

- Click "**Register Now**"

- Complete the registration form with your preferred email address; first and last names; and allocate a password.

The password must include at least one uppercase letter, one lowercase letter, one number, and one non-alphanumeric character.
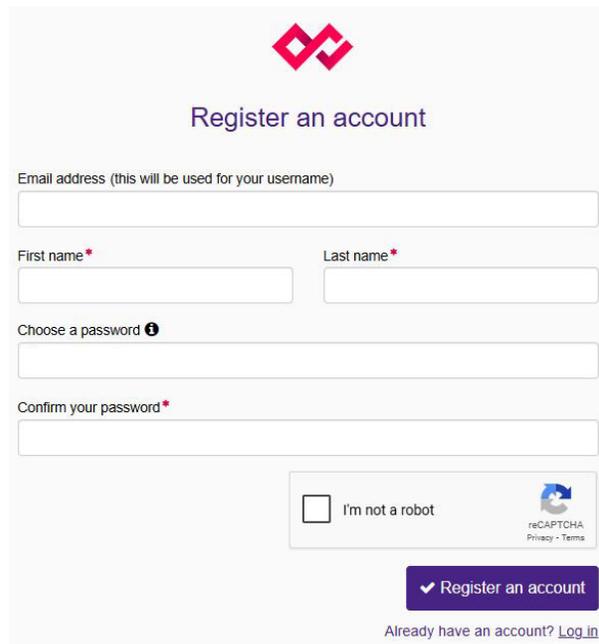
Register an account

Email address (this will be used for your username)

First name* Last name*

Choose a password ⓘ

Confirm your password*

I'm not a robot — reCAPTCHA

✔ Register an account

Already have an account? Log in

Welcome to St Vincent's Application for Governance and Ethics

👥 Log in with SAML

OR

User name*

Password*

👁 Show password

➔ Log in

Can't access your account? Reset your password

Don't have an St Vincent's Application for Governance and Ethics account? Register now

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SAGE Registration Error

- If you receive this error, it is because you already have an inactive SAGE account. please reset your password to reactive your account.

- Go to https://research.svhm.org.au/ and select "Reset your password"

  Can't access your account? Reset your password

- Enter your email address in the Username field.
  Hit "**Reset password**". You will then receive a password reset link via email.
  Please follow the prompt to reset your password.

If you still have issues with login, please contact research.directorate@svha.org.au

Register an account

Registration was unsuccessful. Please correct the error(s) and try again.
- Sorry we were not able to register an account for you. Please contact your system administrator

Reset password

Enter your user name*

☐ I'm not a robot   reCAPTCHA
Privacy - Terms

✔ Reset password

Already have an account? Log in