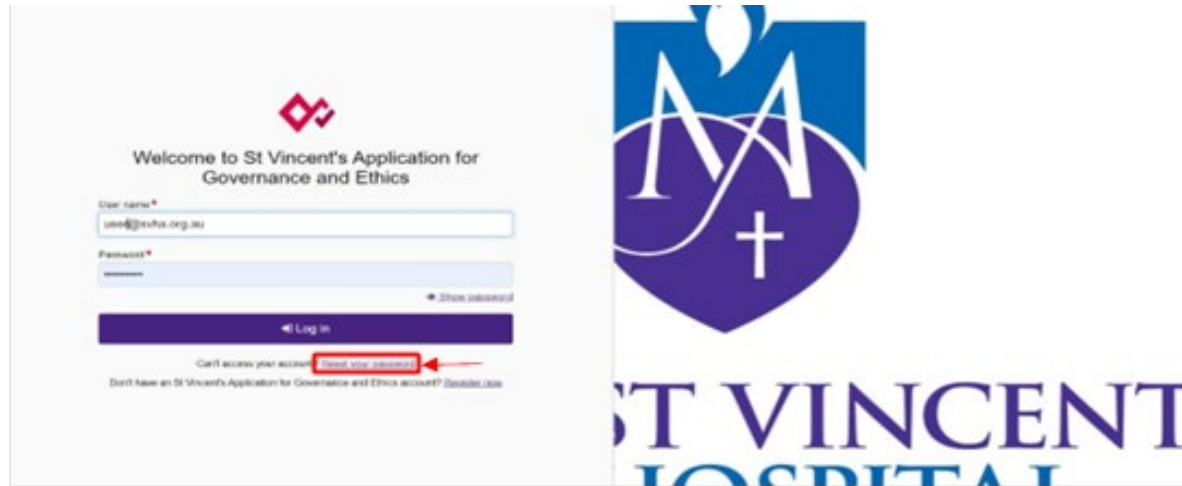


SAGE – Quick Reference Guides

Safety Event Report

1. Login to SAGE – Login instructions can be found [here](#).



2. Locate your project on SAGE. Most active studies have been migrated and can be found on the PI/CPI's dashboard. Please contact research.directorate@svha.org.au if you have an issue locating the project.

St Vincent's Application for Governance and Ethics

Decisions ✓ Reviews Meetings **Projects**

Project > Projects

Listed below are all the projects you currently have access to.

By clicking a project, its related applications will also be displayed.

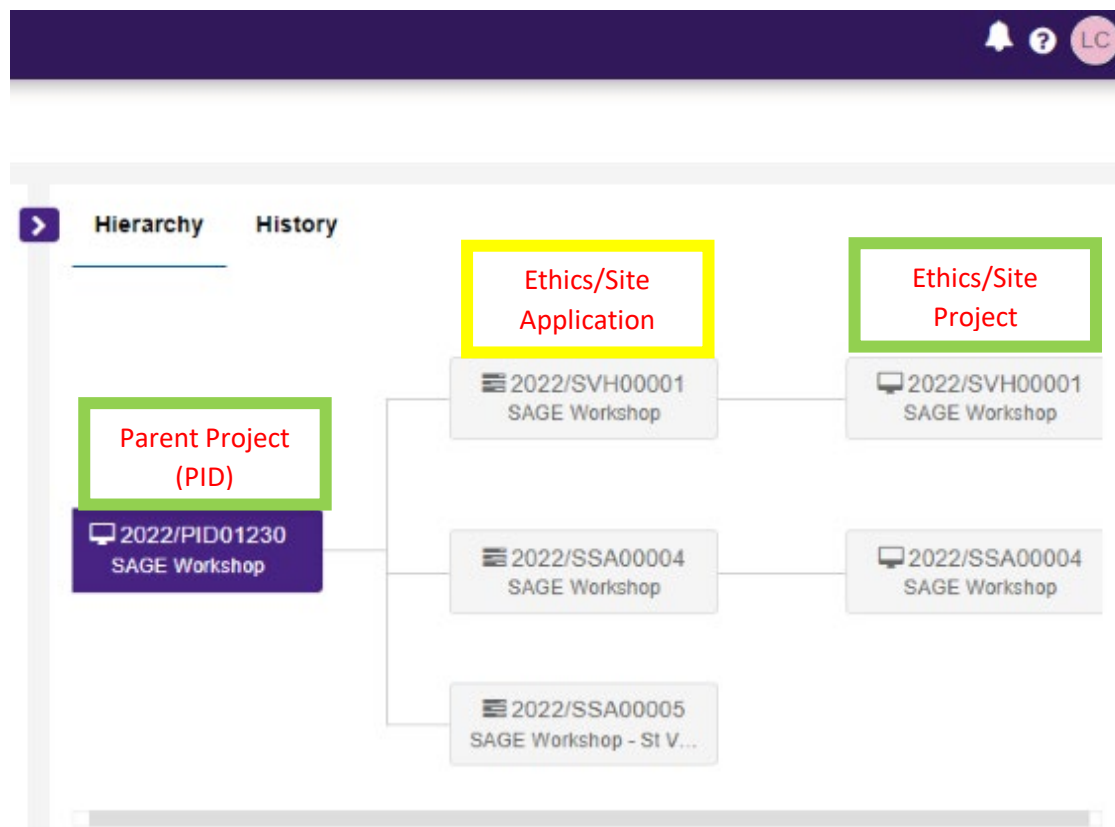
In order to submit an application (ethics and/or site-governance), you must first register the project - you can do that here by selecting the **+New Project** button at the top right.

[Export CSV](#)

TITLE	IDENTIFIER	STATUS	ETHICS APPROVED	EXPIRY DATE	ORGANISATION
061504 - Project Registr...		In Progress			
061503 - Project Registr...		In Progress			
061500 - Project Registr...		In Progress			
061499 - Project Registr...		In Progress			
061497 - Project Registr...		In Progress			
061432 - Project Registr...		In Progress			
061423 - Project Registr...		In Progress			
061422 - Project Registr...		In Progress			
061421 - Project Registr...		In Progress			
061379 - Project Registr...		In Progress			

< Previous **1** 2 3 4 Next >

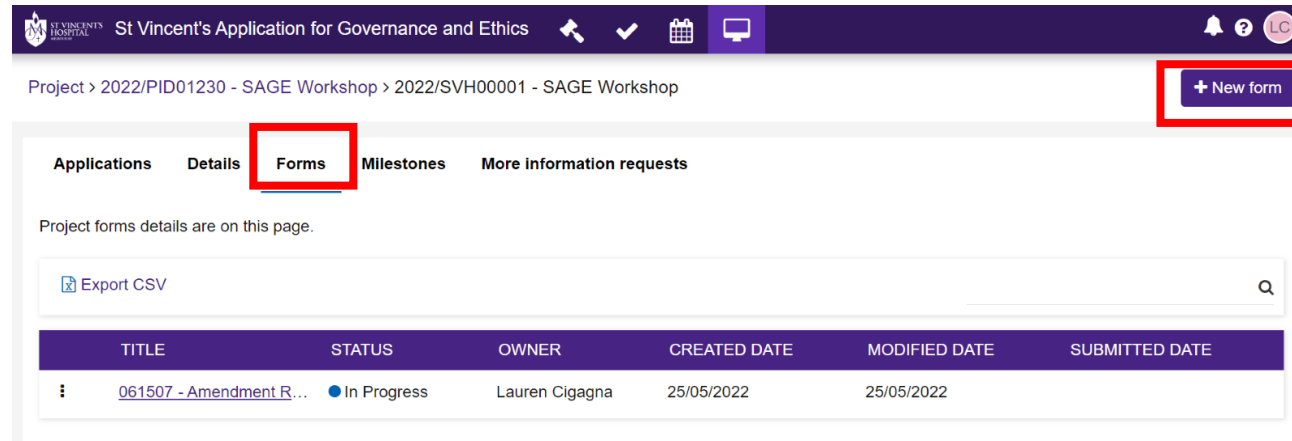
3. Under **'Hierarchy'** select the post-approval project branching from the ethics/governance application, depending on the amendment type.



Note: It may be useful to become familiar with 'Applications' and 'Projects' within SAGE.

- i **Applications** will be generated during the submission stage. Depending on whether you complete it on SAGE or ERM, it may be edited, submitted, viewed for approval status and/or resubmitted. See more details [here](#).
- ii Once the application has been approved, an ethics/site project will be created. For any post-approval management (Amendment, Breach Report etc.), you will need to locate the specific **Ethics Project (SVHxxxxx) or Site project (SSAxxxxx)**.

4. Click '+New form' and then 'Safety Event Report'.



St Vincent's Application for Governance and Ethics

Project > 2022/PID01230 - SAGE Workshop > 2022/SVH00001 - SAGE Workshop

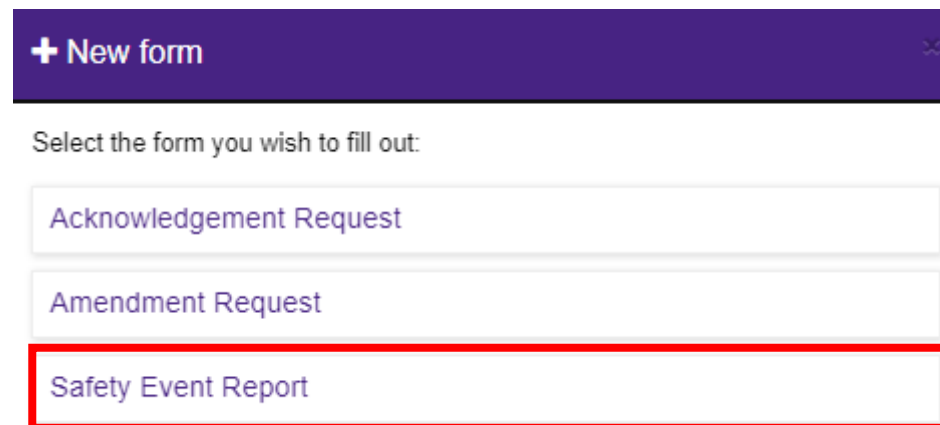
+ New form

Applications Details **Forms** Milestones More information requests

Project forms details are on this page.

Export CSV

TITLE	STATUS	OWNER	CREATED DATE	MODIFIED DATE	SUBMITTED DATE
061507 - Amendment R...	In Progress	Lauren Cigagna	25/05/2022	25/05/2022	



+ New form

Select the form you wish to fill out:

Acknowledgement Request

Amendment Request

Safety Event Report

5. Select safety event type:

- Urgent Safety Measure (USM)
- significant Safety Issue (SSI)
- Suspected Unexpected Serious Adverse Reaction (SUSAR)
- Unanticipated Serious Adverse Device Effect (USADE)
- Temporary halt of a trial for safety reasons
- Early termination of a trial for safety reasons

Safety Event Type*

Please select the correct safety event type in the drop-down menu below. *

|Type to search

Urgent Safety Measure (USM)

Significant Safety Issue (SSI)

Suspected Unexpected Serious Adverse Reaction (SUSAR)

Unanticipated Serious Adverse Device Effect (USADE)

Temporary halt of a trial for safety reasons

Early termination of a trial for safety reasons

For any further information on which safety event type you need to submit, please contact sae.clinicaltrials@svha.org.au to facilitate the safety report acknowledgement.

6. Complete the relevant sections that will appear depending on your safety event type.
 - a. If you have already completed the safety report form, you may also upload it in this section without filling in the rest of the form again.

Select **Yes** below, and upload the form in the upload section in the next page.

Has the Safety Report form been completed by the sponsor of this study?

Yes

No

Supporting Documents Upload

← Previous

Next →

i Please upload the completed and signed safety report form below.

+ Add document

You may submit additional documents, if they are related to this event (optional)

7. Once completed, click the **'Submit'** button. The PI/CPI, Administration Contact and Reporter will automatically receive an email notification that the report has been submitted, and the RGU will be able to process on SAGE.

You DO NOT need to send another email to the RGU for submitting a safety event report. However, if you do not receive a response from RGU within 10 business days, please follow up at sae.clinicaltrials@svha.org.au.