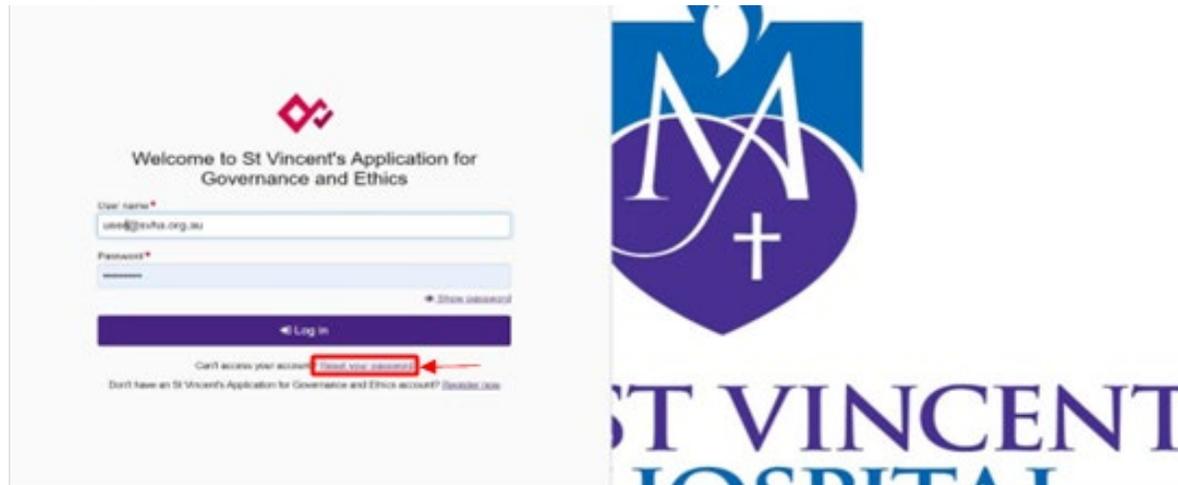


How to submit a Breach Report on SAGE

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.

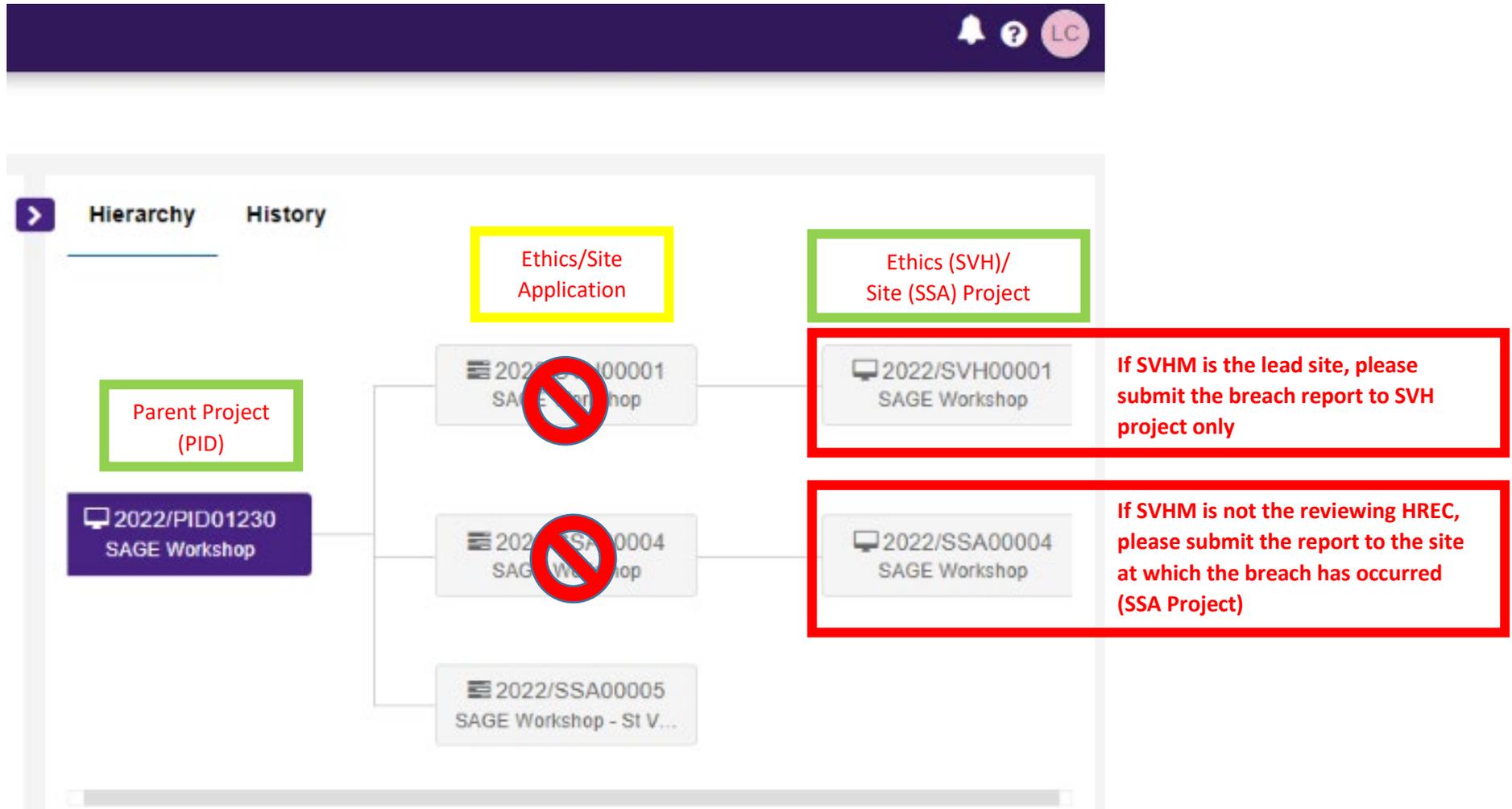
In order to submit an application (ethics and/or site-governance), you must first register the project - you can do that here by selecting the **+New Project** button at the top right.

[Export CSV](#)

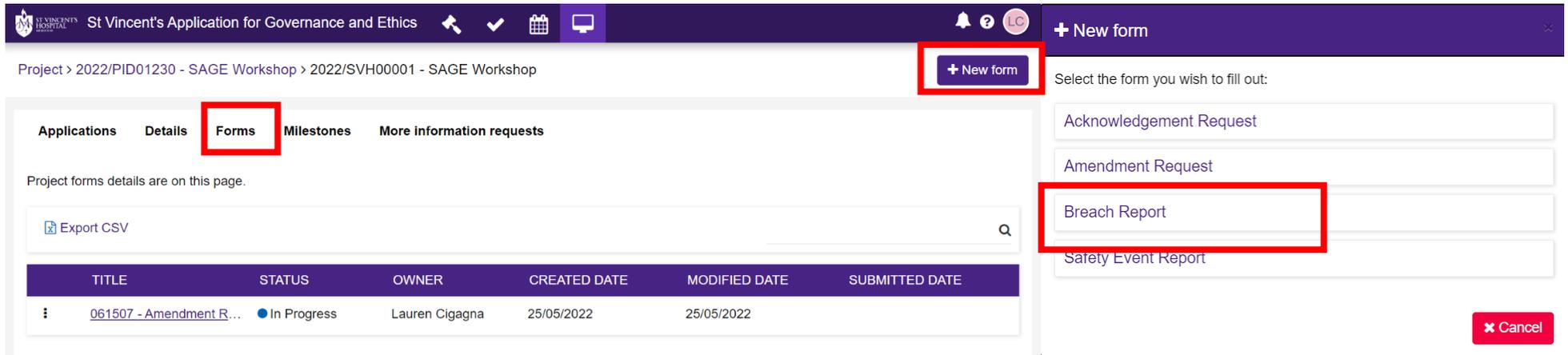
TITLE	IDENTIFIER	STATUS	ETHICS APPROVED	EXPIRY DATE	ORGANISATION
061504 - Project Registr...		In Progress			
061503 - Project Registr...		In Progress			
061500 - Project Registr...		In Progress			
061499 - Project Registr...		In Progress			
061497 - Project Registr...		In Progress			
061432 - Project 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 either the Ethics or Site Project
 - Please submit serious breach reports to the reviewing HREC and the RGO site at which the breach occurred



4. Click '+New form' and then 'Breach Report'.



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

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	

Select the form you wish to fill out:

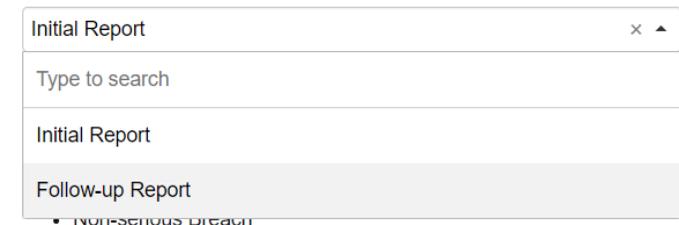
- Acknowledgement Request
- Amendment Request
- Breach Report**
- Safety Event Report

Cancel

5. Is this a new report or a follow-up report?

- Select **Initial Report** if this is a new Breach and you have not reported this previously
- Select **Follow-Up Report** if you have already submitted a report for the same occurrence previously.

Is this a new report or a follow-up report? *



Initial Report

Type to search

- Initial Report
- Follow-up Report**
- Non-serious breach

6. Breach Report Type:

- Serious Breach Report
- Non-serious Breach Report
- Suspected (third-party) Breach Report

If unsure what type of breach report you need submit, you may see more instructions by selecting the “Show detailed description” option

Breach Report Type*

The types of breach report that can be submitted to the HREC are:

- Serious Breach
- Non-serious Breach
- Suspected (Third Party) Breach

Show Detailed Description of Breach Report Types

7. Complete the relevant sections that will appear depending on the type of breach selected.

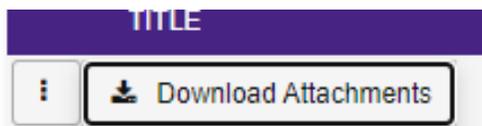
Serious Breach Report	Non-Serious Breach Report	Suspected (third-party) Breach Report
<div style="border: 1px solid #ccc; padding: 5px;"> <p>Project Details and Breach Type ✔</p> <p style="background-color: #0056b3; color: white; padding: 2px;">Research Project Details</p> <p>Details of the serious breach</p> <p>Details of any action taken to date</p> <p>Actions recommended by the sponsor (on advice of Principal Investigator)</p> <p>Supporting Documents Upload</p> <p>Declaration</p> </div>	<div style="border: 1px solid #ccc; padding: 5px;"> <p>Project Details and Breach Type ✔</p> <p style="background-color: #0056b3; color: white; padding: 2px;">Research Project Details ✔</p> <p>Details of the non-serious breach - Deviation</p> <p>Are there any actions recommended by the sponsor</p> <p>Supporting Documents Upload</p> <p>Declaration</p> </div>	<div style="border: 1px solid #ccc; padding: 5px;"> <p style="background-color: #0056b3; color: white; padding: 2px;">Project Details and Breach Type ✔</p> <p>Research Project Details ✔</p> <p>Details of Suspected Breach</p> <p>Supporting Documents Upload</p> <p>Declaration</p> </div>

8. 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 it on SAGE.

9. After submitting the report

- You **DO NOT** need to send another email to the RGU for submitting a breach report. However, if you do not receive a response from RGU within 10 business days, please follow up at research.ethics@svhm.org.au
- To see your submitted Breach report form, click on the Option button and select download documents

TITLE	STATUS	OWNER	CREATED DATE	MODIFIED ↓ DATE	SUBMITTED DATE
 068157 - Breach Report	● Submitted	Sue Sie Ngeow	26/09/2023	26/09/2023	26/09/2023



- You may disseminate the attachments via email to sponsors or other parties.