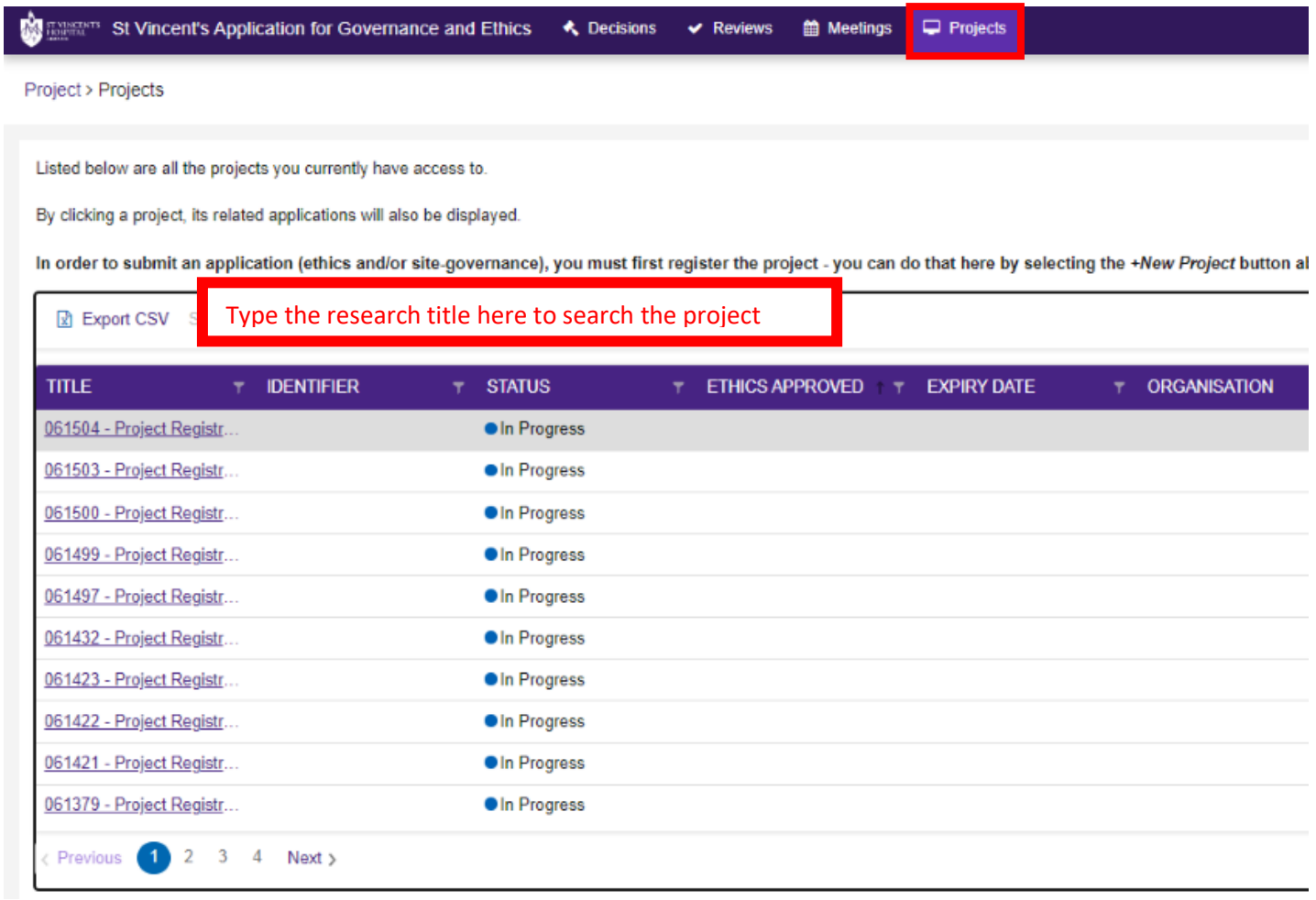
SAGE – Quick Reference Guides

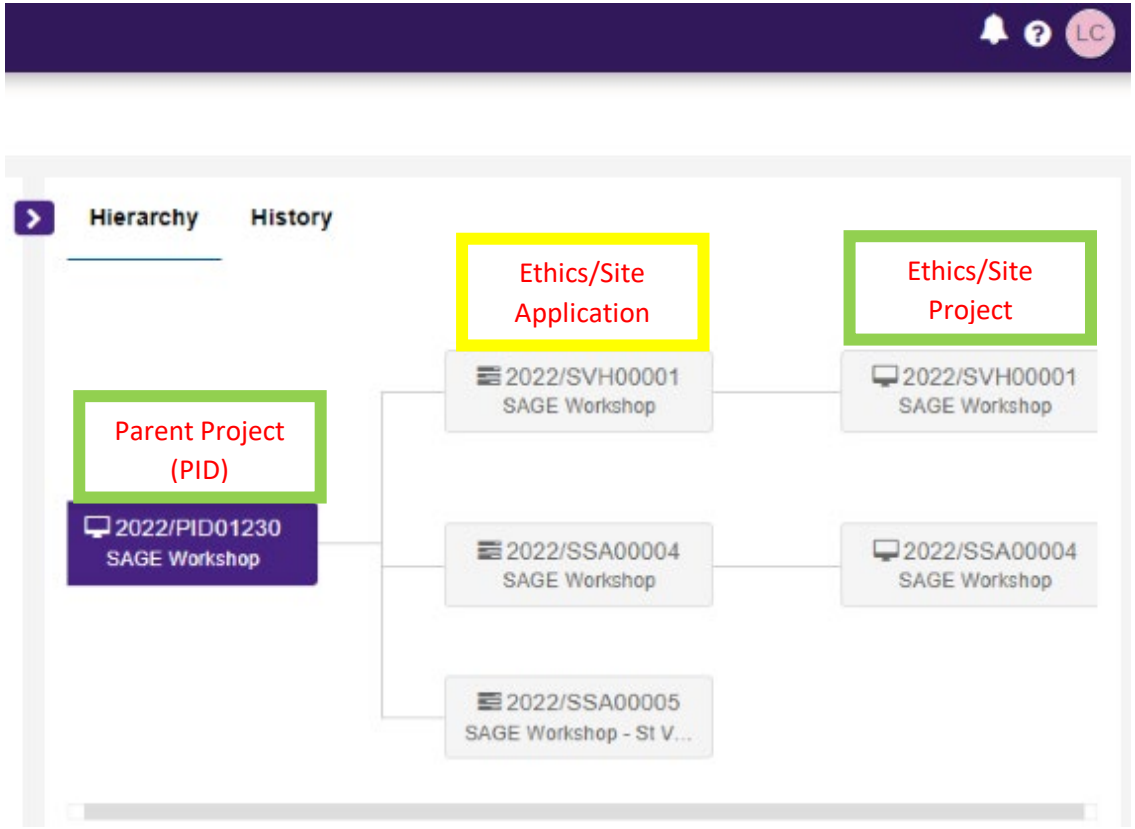
Safety Event Report

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 al
Export CSV
Type the research title here to search the project
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.

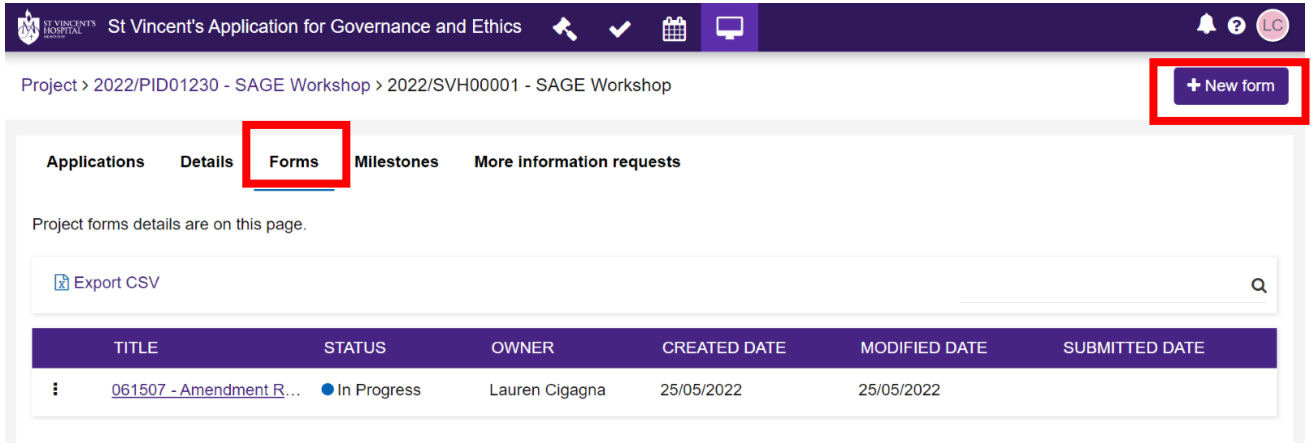


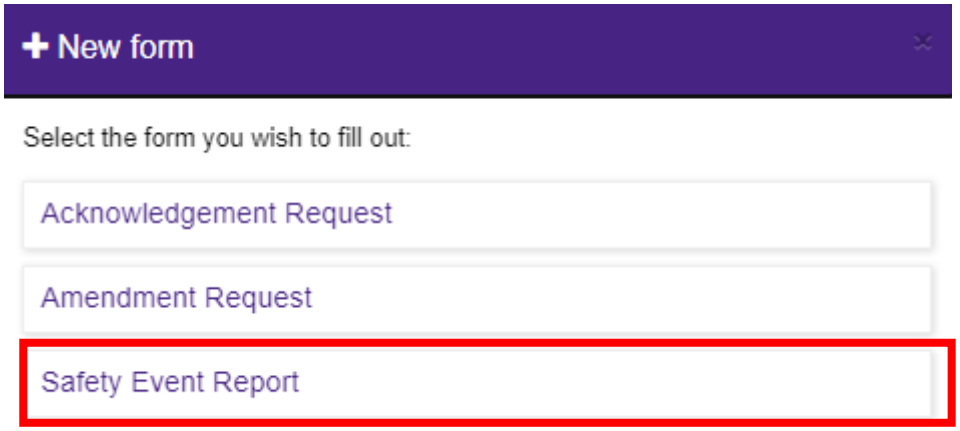
Note: It may be useful to become familiar with 'Applications' and 'Projects' within SAGE.

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.

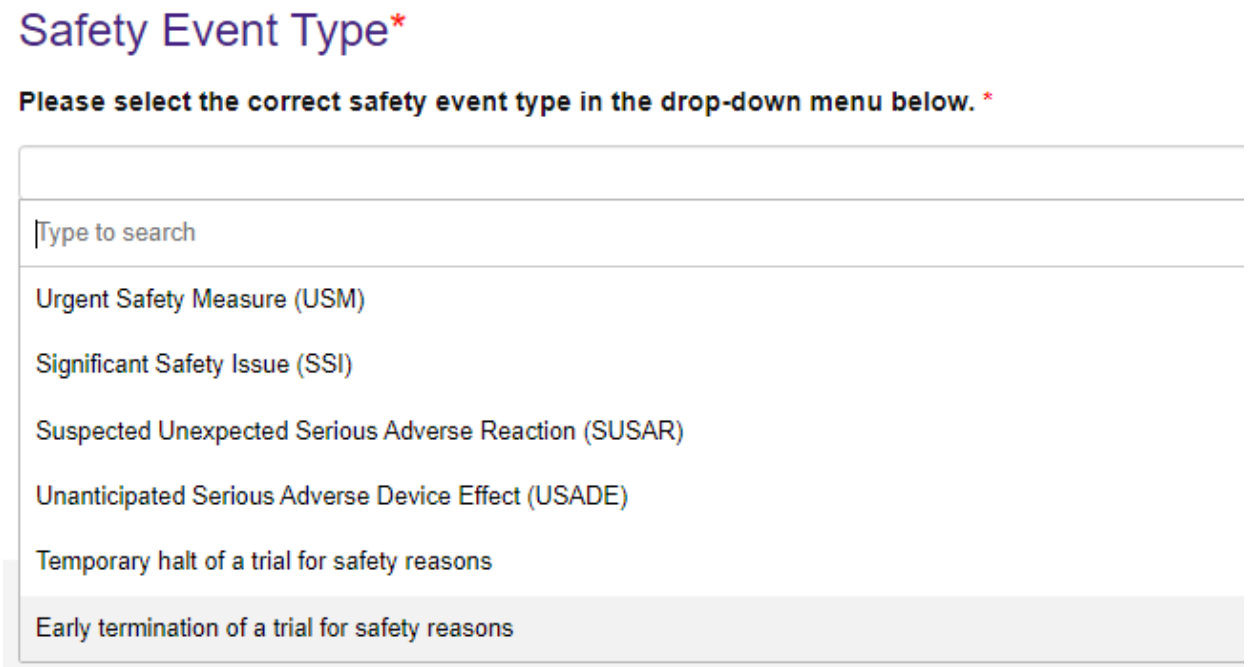
ii Once the application has been approved, an ethics/site project will be created. For any post-approval management (Amendment, Breach Report etc.), you will need to locate the specific **Ethics Project (SVHxxxxx) or Site project (SSAxxxxx).**

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



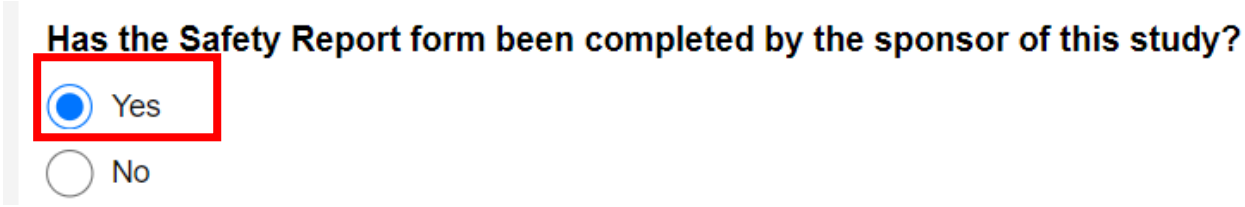


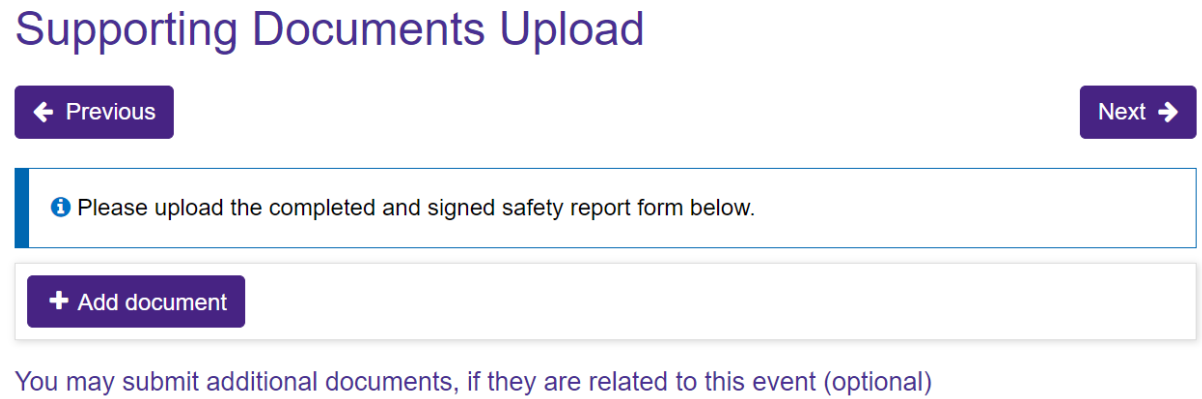
5. Select safety event type:
    - Urgent Safety Measure (USM)
    - significant Safety Issue (SSI)
    - Suspected Unexpected Serious Adverse Reaction (SUSAR)
    - Unanticipated Serious Adverse Device Effect (USADE)
    - Temporary halt of a trial for safety reasons
    - Early termination of a trial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



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.





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.