How to submit an Annual Safety Report on SAGE

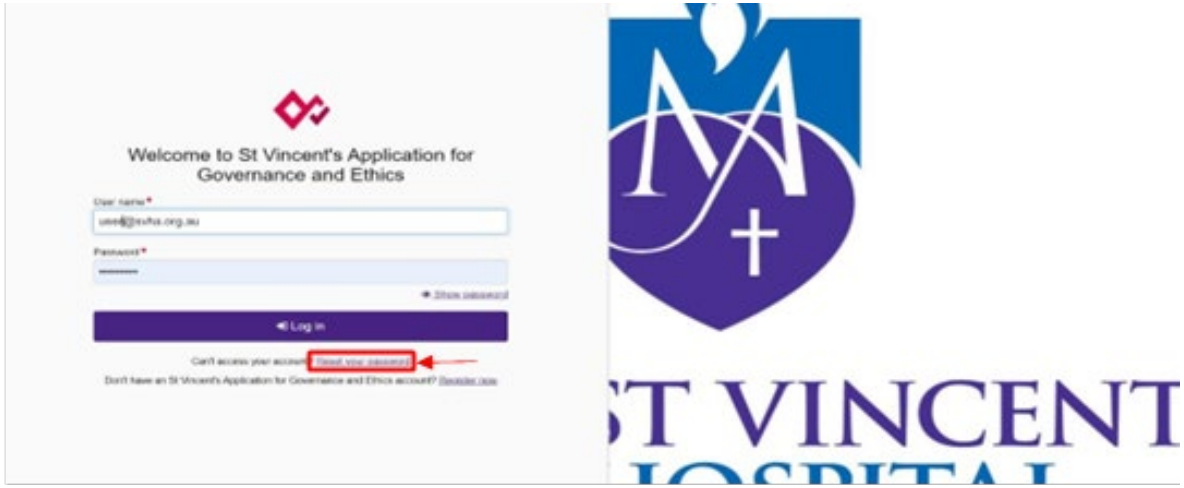
Overview

- Annual Safety Reports (ASR) are mandatory for **clinical trials** involving an investigational medicinal product or investigational medical device.
- This form should be used by the sponsor to provide the reviewing Human Research Ethics Committee (HREC) with a summary of the evolving safety profile of the project.
- The ASR is **due on the anniversary of the HREC Approval**. The completion and submission of an ASR are part of the conditions of HREC approval for all projects. For example, if a research project is approved by SVHM HREC on 2 July 2023, the first ASR will be due on 2 July 2024.
- The sponsor is responsible for reporting to the reviewing HREC, in accordance with Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (NHMRC, 2016). **ONLY the Sponsor or CPI can sign-off and submit the ASR Form.**
- The ASRs are separate from the Annual Progress Reports, which are due on 1st May each year. For more information regarding the Annual Progress Reports, please refer to this Annual Report Submission guide.
- For further information, please contact Reception on 03 9231 6970 or email SAE.ClinicalTrial@svha.org.au

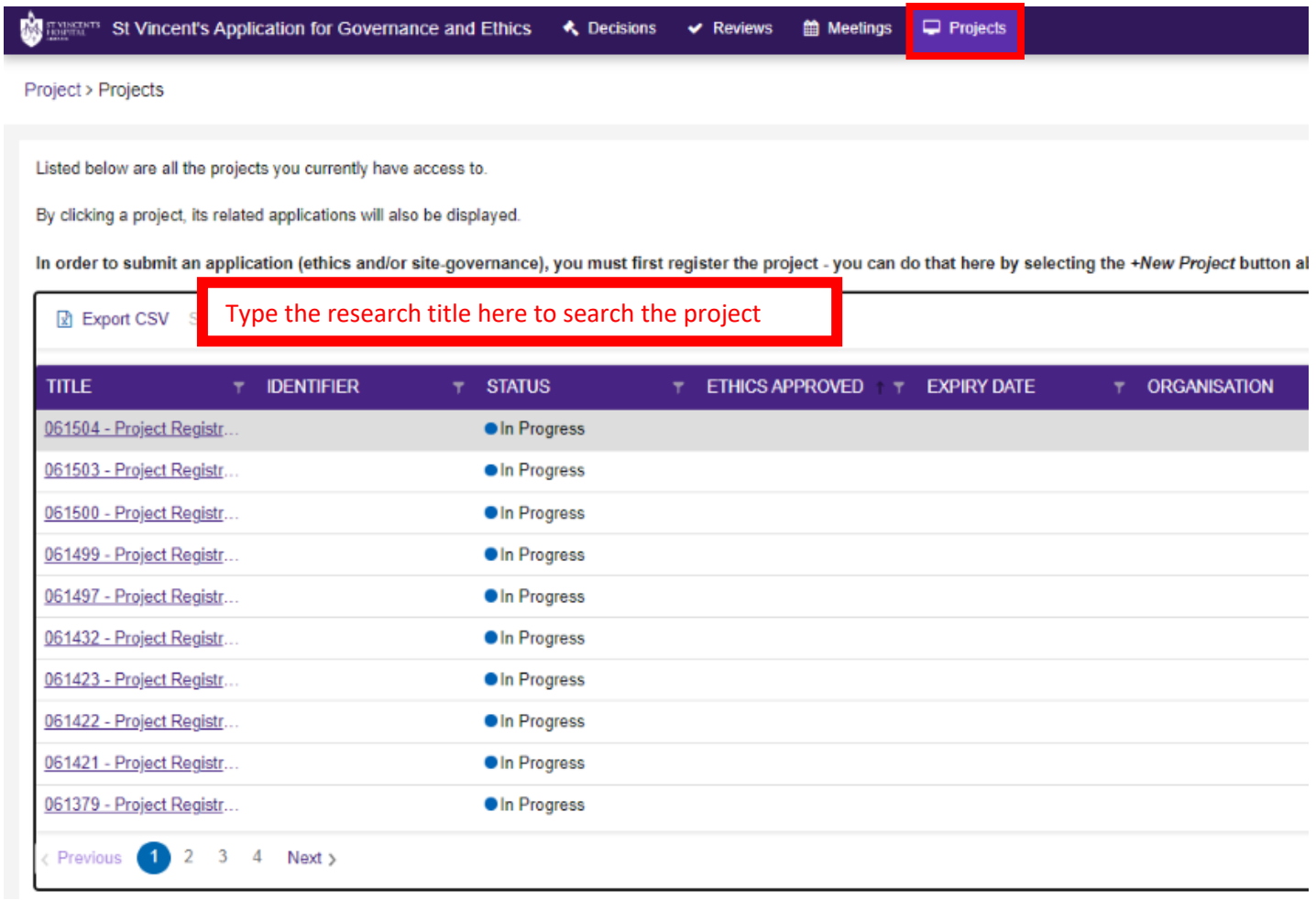
How to locate the Annual Safety Report Form on SAGE

From 14 February 2024 onwards, all ASRs need to be submitted and managed via 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 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...
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061500 - Project Registr...
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061499 - Project Registr...
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061423 - Project Registr...
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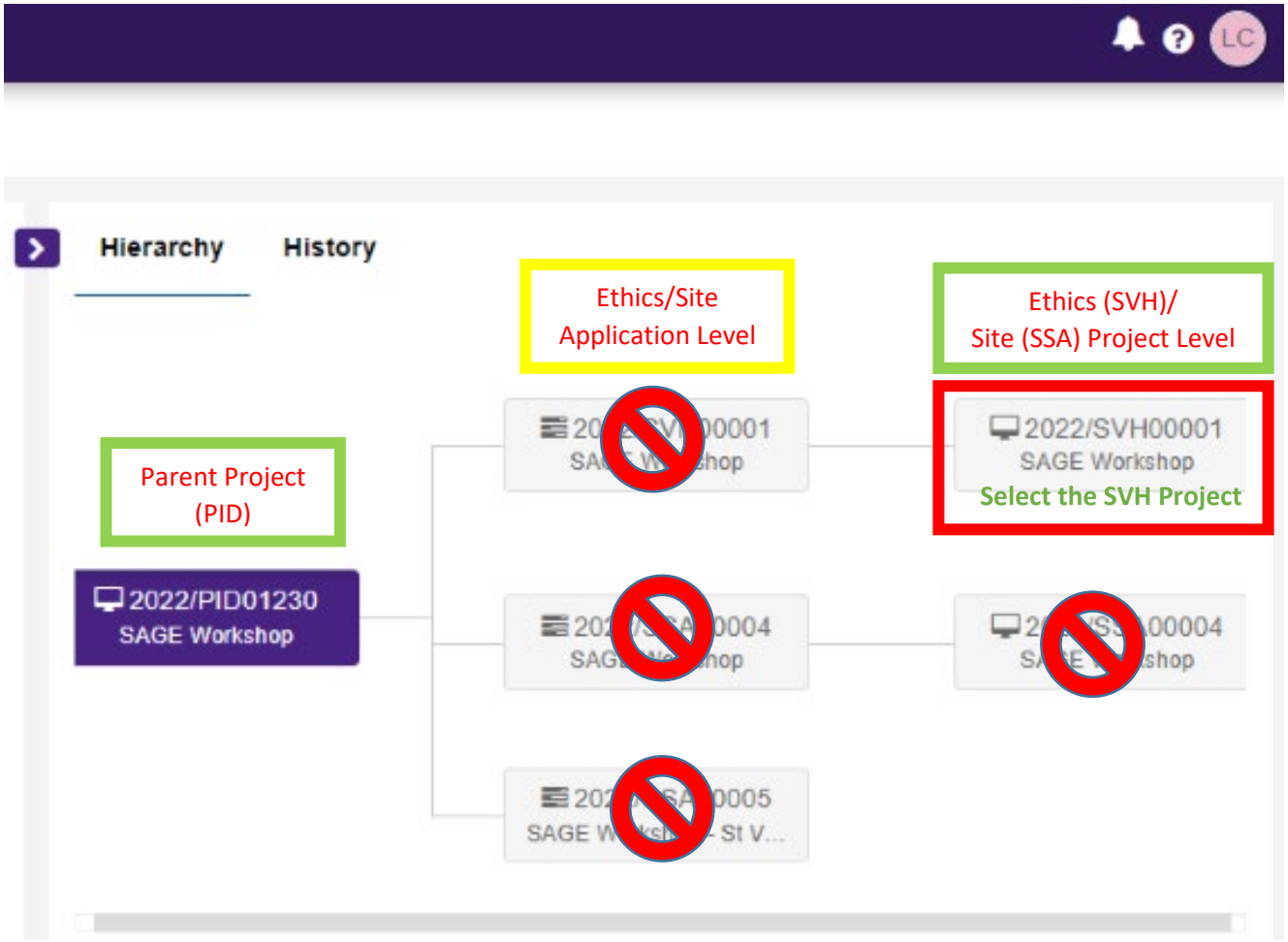
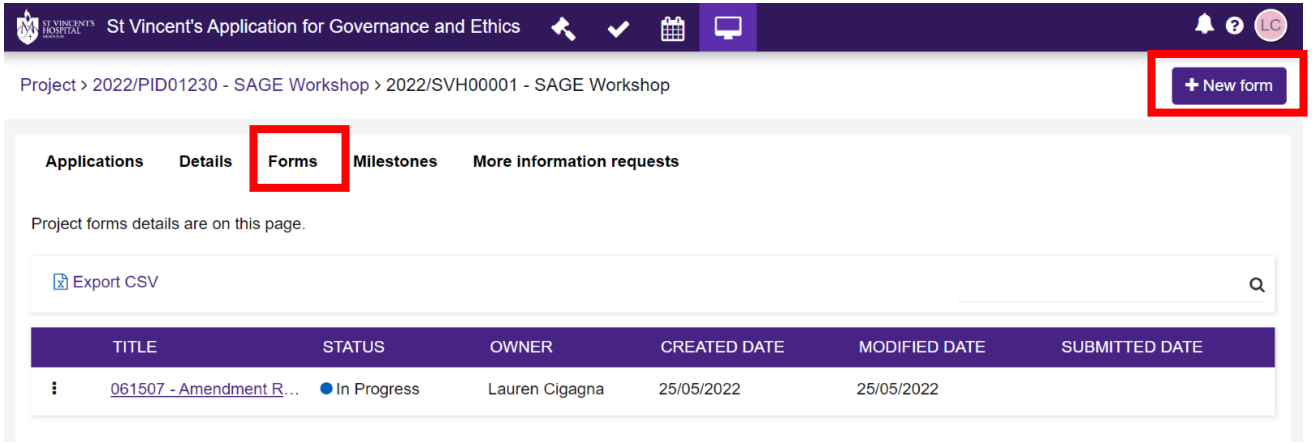
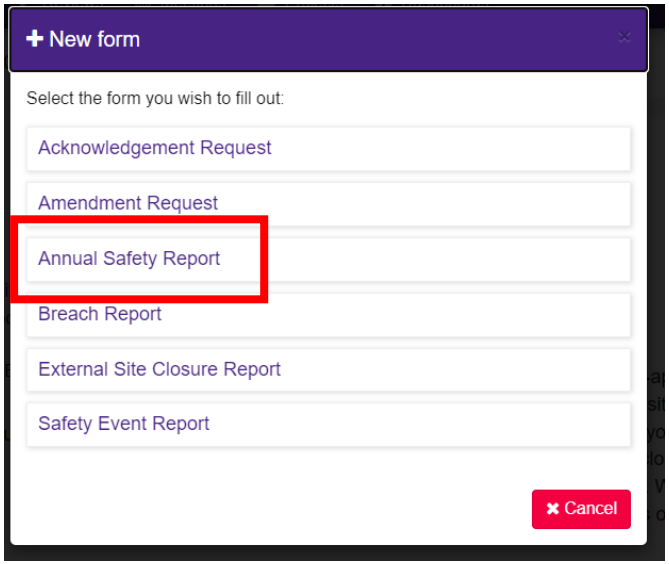
061422 - Project Registr...
In Progress
061421 - Project Registr...
In Progress
061379 - Project Registr...
In Progress
Previous
1
2
3
4
Next

3. Under **'Hierarchy'** please select the SVH Project.
   The ASR is only relevant to the SVH Project – the ASR is an ethics requirement to be reviewed by the HREC; it is not a site-specific (RGO) requirement.
   If SVHM is not the lead HREC, please submit the ASR to the appropriate lead HREC. However, after the lead HREC has acknowledged the ASR, you may choose to submit it under the Site branch for acknowledgement.

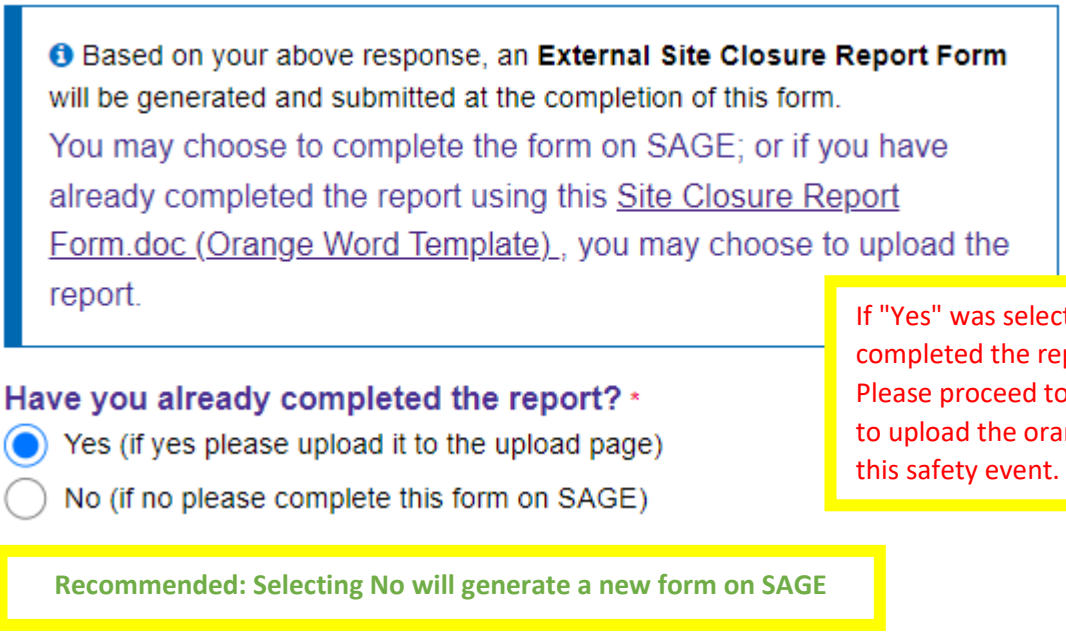


4. Click **'+New form'** and then **'Annual Safety Report'**.





5. You have two options to complete the ASR



If "Yes" was selected, you have indicated that the sponsor has completed the report. You do not need to refill the form. Please proceed to the Supporting Documents Upload section to upload the orange form and all of the documents related to this safety event.

6. For the question below,

- Please select “No” if you are submitting a new report;
- Please select “yes” if you are resubmitting the same report after receiving a query from the RGU.

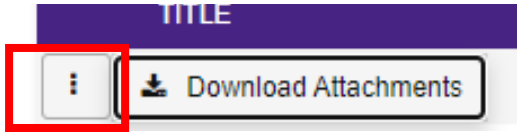
7. Once completed, click the **'Submit'** button. Please note that only the Sponsor/ CPI can submit the ASR. Please contact research.directorate@svha.org.au if you are a sponsor or CPI, but you cannot find submit the report form

8. 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 site closure report. However, if you do not receive a response from RGU within 10 business days, please follow up at svhm.ResearchAnnualR@svha.org.au

   - To see your submitted Site Closure report form, click on the Option button and select download documents



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