What are the annual reporting requirements and how to submit them?

Annual Reports are mandatory

The completion and submission of an annual report are mandatory for all projects as a condition of ethical approval and governance authorisation. Failure to submit a satisfactory annual report will result in the withdrawal of HREC approval and/or governance authorisation, leading to **study suspension**. As a result, all study activities must be halted until the approval is reinstated following the submission and approval of a satisfactory annual report.

The annual report is due 1 May annually. Starting in 2025, the annual progress report cannot be submitted before 1 May to ensure continuous reporting with no gaps between reports, maintaining data completeness and accuracy.

All annual reports must be submitted via SAGE.

For any questions related to annual reports, please contact Research Integrity and Compliance Team on 03 9231 6972 or email svhm.ResearchAnnualR@svha.org.au

For more information regarding the annual report submission process, please click on each relevant topic below:

- Submission timeline
- Reporting level and submission responsibilities
- Study statuses
  - Study statuses within the HREC Form
  - Study statuses within the RGO Form
- How to locate your annual report form
  - Locating Annual Project Progress/Final Report (HREC Form) or Annual Site Progress/Closure Report (RGO Form)
  - Locating an External Site Closure Report Form
- Queries and revision to the annual reports
- How to download previously submitted reports

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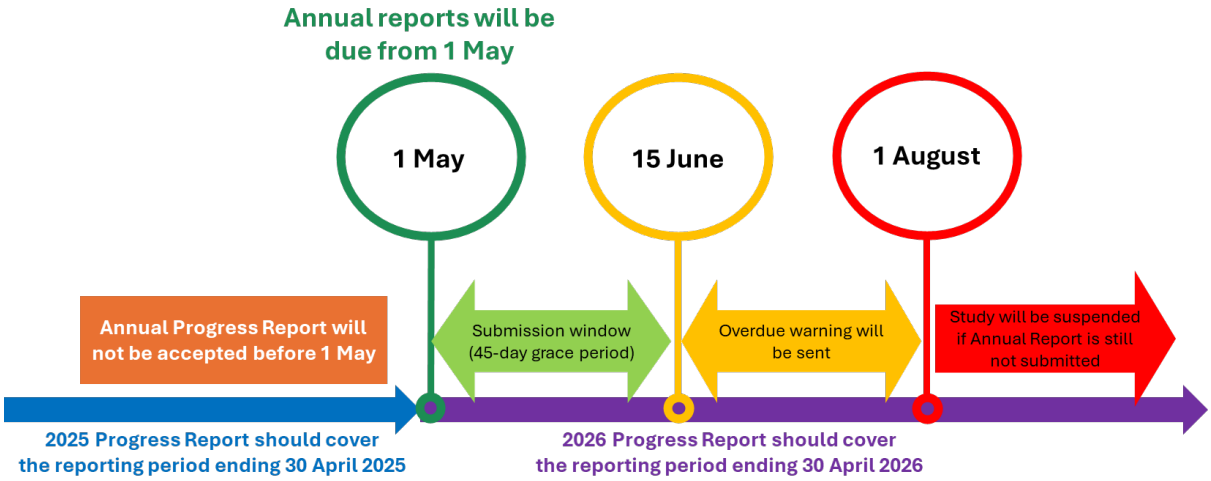
Submission timeline



The submission deadline is May 1st annually, starting from the following year of the approval date until the project completion.

Note: Starting in 2025, Annual Progress Reports cannot be submitted before 1 May. The submission button on SAGE will be disabled if you attempt to submit a progress report form before 1 May.

Submission of final reports is required to inform the HREC about the completion or abandonment of a project.

Failure to submit progress reports within 45 days after the 01 May deadline may result in the study suspension.

Acknowledgement of a submitted annual progress report will generally be provided within 2 months of report submission - this timeline may be extended due to the significant volume of reports received.

Reporting level and submission responsibilities

All Annual Reports and Final Reports are to be submitted under the relevant projects on SAGE, see how to locate your annual report forms.

1. **Progress/Final Report (HREC Form) -** Can only be submitted by the CPI or Sponsor on SAGE.
2. **Site Report/Closure Form (RGO Form) -** Can only be submitted by the site PI on SAGE.
3. **External Site Closure Form (HREC Form) -** Can only be submitted by the CPI or Sponsor on SAGE.

Different report forms are required depending on the project types. Please refer to the following table for what report types are required for your project, and whose responsibility it is to submit.

Project Types	Report Form Required	Whose Responsibility to submit
Ethics only project *Study reviewed by SVHM HREC, but no SVHM site is involved in the study*	Progress/Final Report (HREC Form at the SVH project level)	• The **CPI** for an investigator-initiated study; • A **sponsor representative** for commercially-sponsor study
Governance only project *Study reviewed by an external HREC, SVHM as participating site*	Site Report/Closure Form (RGO Form at the SSA project level)	The **site Principal Investigator** must submit the site report.
Both Ethics and Governance project (Single-Site Study) *where SVHM is both the HREC and the only participating site*	Site Report/Closure Form only (RGO Form at the SSA project level)	The **site Principal Investigator** must submit the site report.
Both Ethics and Governance project (Multisite Study) *where SVHM is the HREC and one of the participating sites*	Both HREC and RGO report forms are required (at both SVH and SSA project levels)	**HREC Report:** • The **CPI** for an investigator-initiated study; • A **sponsor representative** for commercially-sponsor study **RGO Report**: PI only
Ethics project with a closure of an external site *Closure of a non-SVHM RGO site approved under SVHM HREC*	External Site Closure Form (at the SVH project level)	• The **CPI** for an investigator-initiated study; • A **sponsor representative** for commercially-sponsor study

If you believe you should have submission access but are unable to submit the form, please contact research.directorate@svha.org.au.

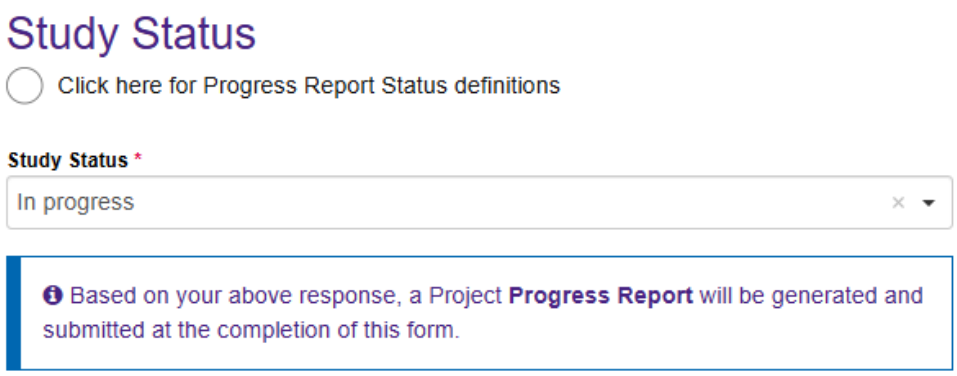
Study statuses will determine whether it is a progress or a final report

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

Study statuses within the HREC Form

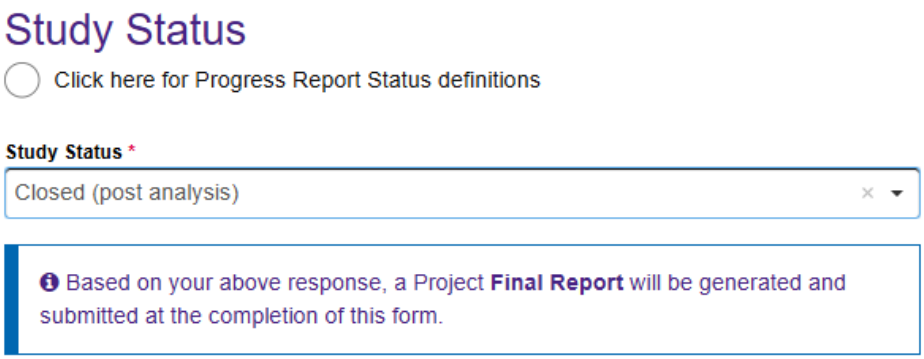
Selecting one of these statuses will generate an **HREC Progress Report**, indicating that the study is ongoing at one or more participating sites and that a future report is expected:

- **Not Yet Commenced:** No clinical activities involving participants (including recruitment) have started.
- **In Progress:** Clinical or study activities have commenced.



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:

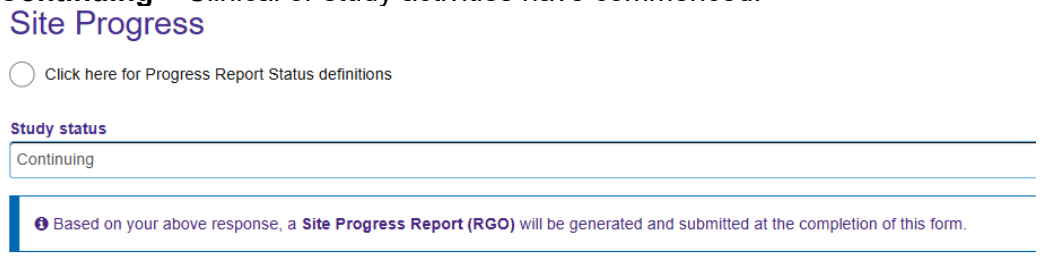
- **Closed (post analysis) –** The study has finished normally; participants are no longer being treated or examined. The database is locked, and data analysis is complete.
- **Abandoned –** The application was approved/authorised, but the project will never commence.
  Terminated – The study started 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 "Complete" or "Closed (post analysis)".



Study statuses within the RGO Form

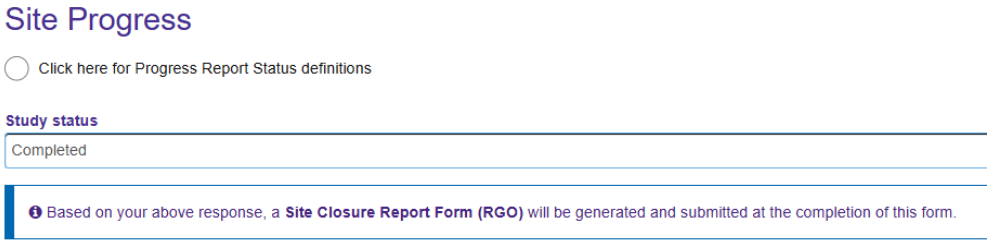
Selecting one of these statuses will generate a Site Progress Report, indicating that the study is ongoing at the site and that a future report is expected:

- **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.



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.

Locating your annual report forms

Locating Annual Project Progress/Final Report (HREC Form) or Annual Site Progress/Closure Form (RGO Form)

Step 1. Login to SAGE

Step 2. Identify your project

Step 3. Navigate to the Milestone menu

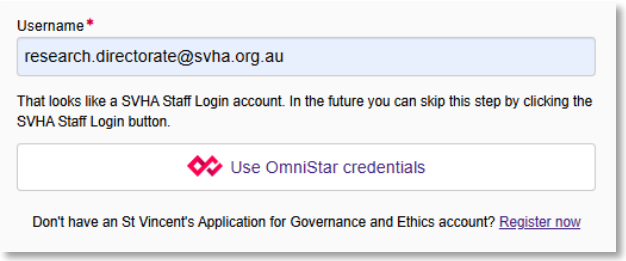
Step 1. Login to SAGE - https://research.svhm.org.au/

For individual St Vincent's staff:

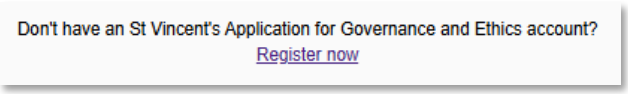
Please use the SVHA Staff Login Option to login using St Vincent's credentials.

For any other users (including shared account users):

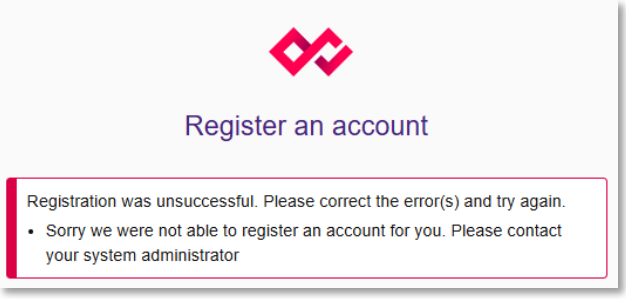
Please enter your username and select "Use OmniStar credentials" to login.



If you are new to SAGE **and haven't got an account, please register a new account.**

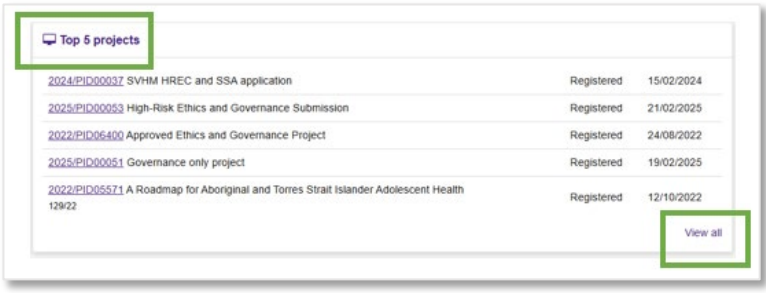


If the account registration is unsuccessful, you may already have an existing account created on your behalf. Please **reset your password** to activate your account.



Step 2. Identify your project

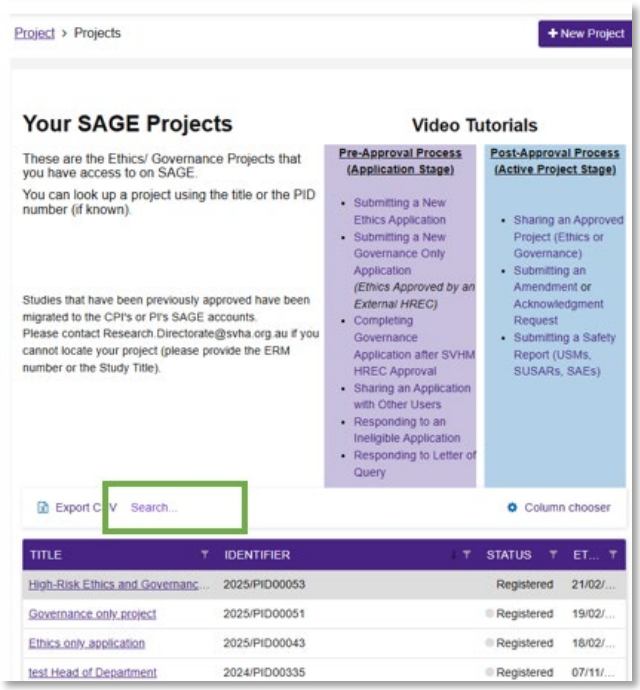
I. **On your Homepage, check the** Top 5 Projects tile.
If your project is not listed, click the "View All**" button.**



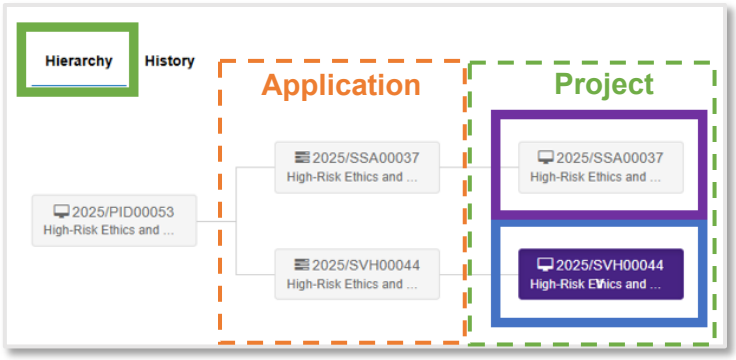
II. All your **registered projects** will be listed here.

Use the Search bar to find your project by **title** or **PID number.**

Select the relevant study.

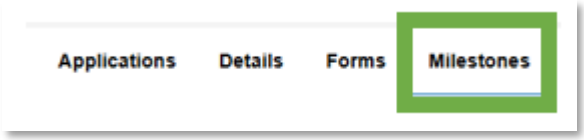


III. Navigate to the **Hierarchy** tab and select the **relevant project** (not the **application**).



Project with an **SVH** ID = St Vincent's **HREC (Ethics level)**
Project with an **SSA** ID = Site-Specific Assessment (RGO level)

Step 3. Navigate to the Milestones menu



Here, you will find a list of pending, submitted, or achieved annual progress/final reports.

IDENTIFIER	MILESTONE TITLE	DETAIL	ORGANISATION	STATUS	DAYS REMAINING	DUE DATE
2022/SVH00201	Progress/Final Report (HREC)	Progress Report	SVHM	Achieved	N/A	30/05/2023
2022/SVH00201	Progress/Final Report (HREC)		SVHM	Achieved	N/A	1/05/2024
2022/SVH00201	Progress/Final Report (HREC)		SVHM	Pending	57 days	1/05/2025

If you cannot locate the report form, it is likely associated with the corresponding project (SSA or SVH project). Refer the reporting level required for your project. If you cannot find any report forms, please contact research.directorate@svha.org.au for assistance.

Locating **the External Site Closure Report Form**

Step 1. Login to SAGE

Step 2. Identify your project

Step 3. Navigate to the Forms menu

Step 1. Login to SAGE - https://research.svhm.org.au/

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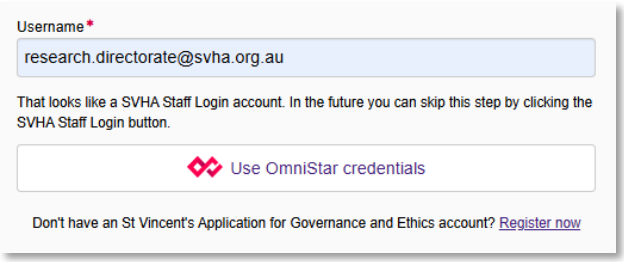
Please use the SVHA Staff Login Option to login using St Vincent's credentials.

For any other users (including shared account users):

Please enter your username and select "Use OmniStar credentials" to login.



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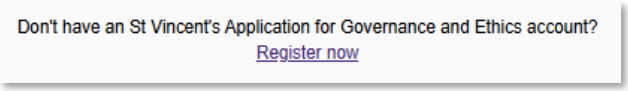

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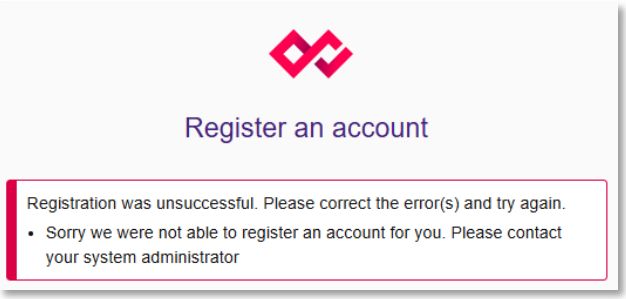

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Step 2. Identify your project

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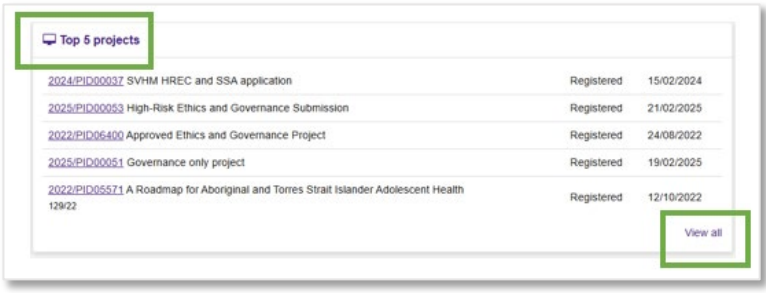
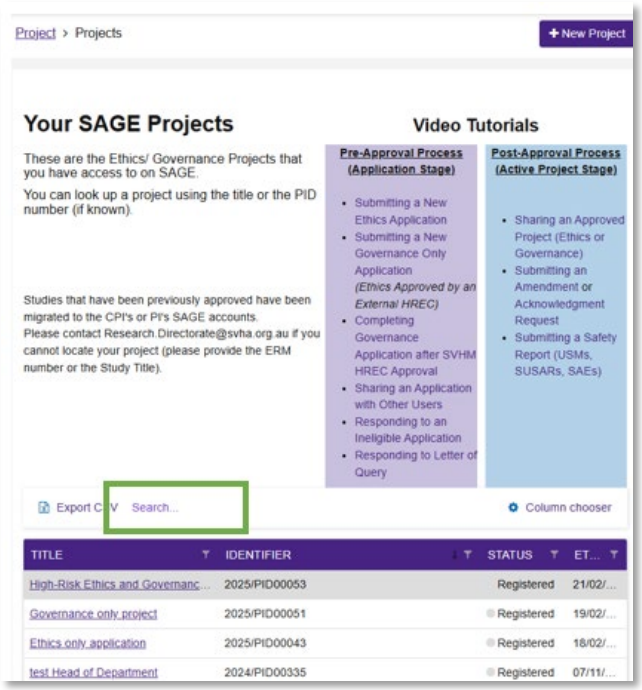
   If your project is not listed, click the "View All**" button.**



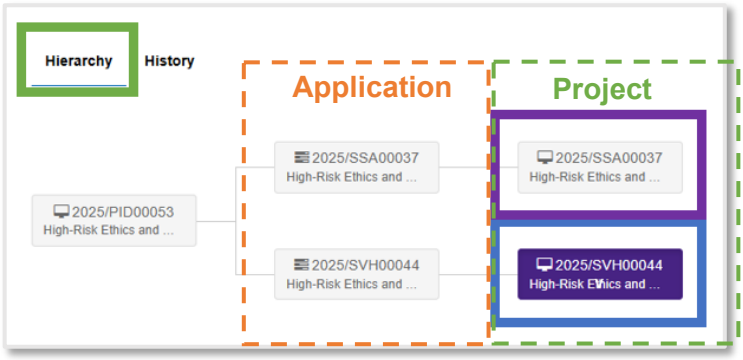
2. All your **registered projects** will be listed here.

   Use the Search bar to find your project by **title** or **PID number.**

   Select the relevant study.



3. Navigate to the **Hierarchy** tab and select the **relevant project** (not the **application**).



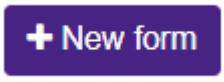
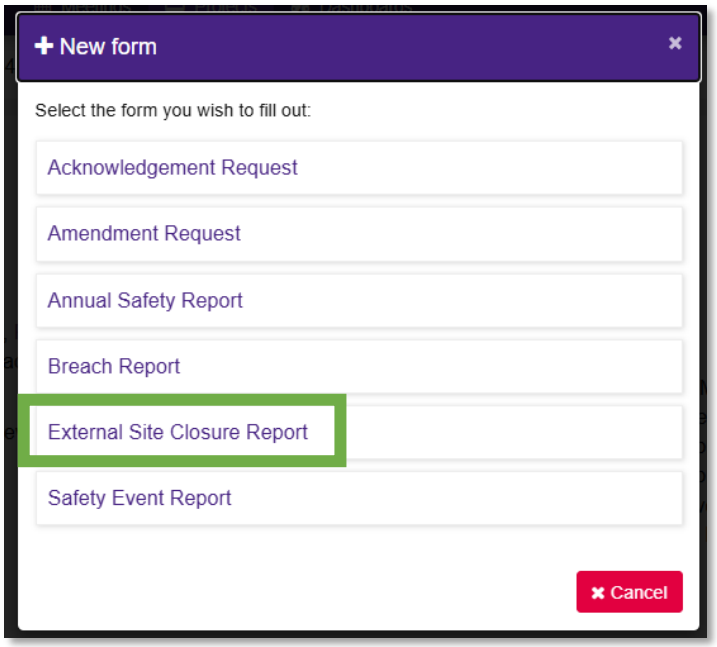
Project with an **SVH** ID = St Vincent's **HREC (Ethics level)**
Project with an **SSA** ID = Site-Specific Assessment (RGO level)

Step 3. Navigate to the Forms menu

1. Navigate to the **Forms Menu**

s

2. Click the "**+New form**" button



3. Select the External Site Closure Report form.