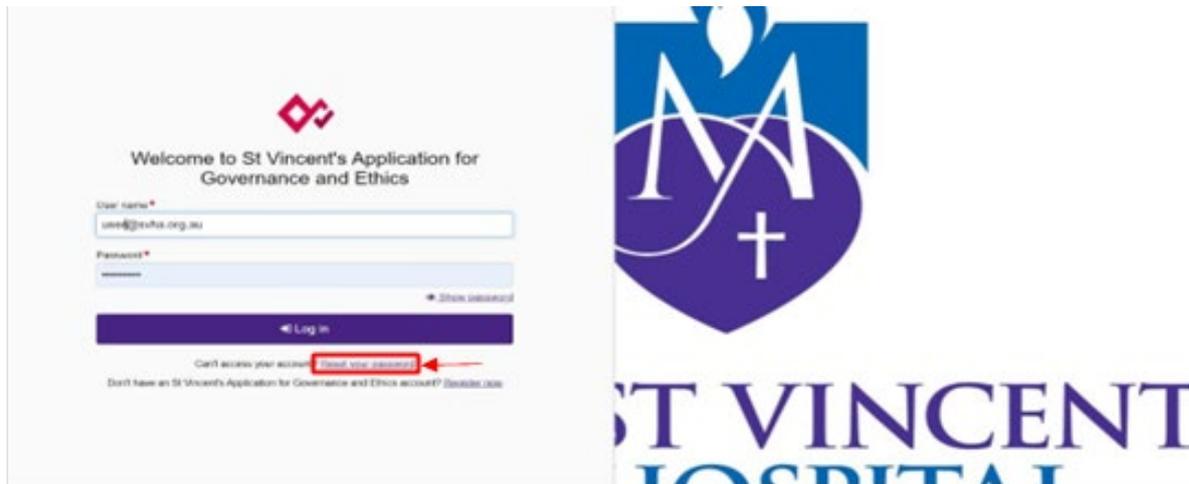


SAGE – Quick Reference Guides

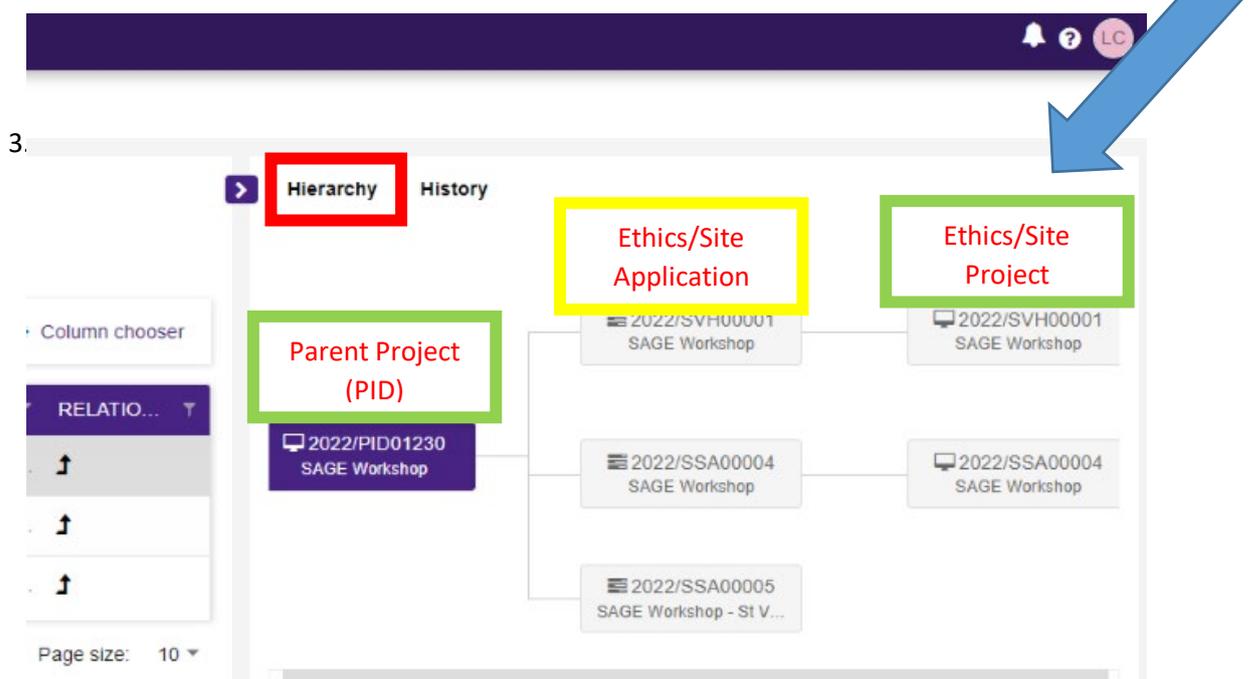
Responding to an Information Request to an Amendment

This guide is applicable for ethics or governance amendments for an approved study. When the RGU/ HREC requests additional information for your amendment request, you will be notified via email with the subject title “Amendment - More information required”. The comments from HREC/RGU will be listed on the email.

1. The email contains the link that directs you to the project to submit your response via SAGE. Please follow the link and log in to access your project.



2. A hierarchy will be shown on the right side of the project viewer. Select the **Ethics or Site PROJECT** where the amendment was initially submitted.



Applications Details Forms Milestones More information requests

Project details are on this page.

Export CSV Search... Column chooser

IDENTIFIER	TITLE	COMMENTS	VERSION	STATUS	OWNER	CREATED...	MODIFIED...	ORGANIS...	RELATION...
2022/SSA00004	SAGE Works...		1.00	Information ...	LC	22/04/2022	23/05/2022	St Vincent's H...	↔
2022/SVH...	SAGE Works...		1.03	Approved	LC	03/05/2022	20/05/2022	St Vincent's H...	↔
2022/PID01230	SAGE Works...			Registered	L			SVHM	↓
2022/SSA...	SAGE Works...		1.00	Completed ...	SN	22/04/2022	21/06/2022	St Vincent's H...	↔

< Previous 1 Next > Page size: 10 ↓

4. Action is required if the status says, "Information Required". You can then access the amendment request form by clicking on the title of the form.

TITLE	STATUS	OWNER	CREATED DATE	MODIFIED DATE	SUBMITTED DATE
061533 - Amendment Request	Approved	Lauren Cigagna	06/06/2022	08/06/2022	06/06/2022
061543 - Amendment Request	Submitted	Sue Sie Ngeow	09/06/2022	09/06/2022	09/06/2022
061658 - Amendment Request	Information Required	Jarvis Sukanto	11/08/2022	11/08/2022	

5. Amend the form accordingly to the comments made by the HREC Committee. In this example we will add an additional document as a clarification letter.

Project Details and Amendment Type Document upload Previous Validate Save Next

General Amendment Process

Document upload

- This section allows the applicant to submit amended versions of documents already approved by the HREC or to submit new documents.
- It is mandatory to upload a copy of the Fee form below.
- Only upload documents to be reviewed by the HREC. Site Specific documents that relate to this amendment, should be submitted directly to the RGO using the site amendment form.
- Click the 'Add Another' button to add one or more documents.
- If there are no documents to be uploaded, progress to the next section.
- A tracked copy of a changed/updated document is required to be uploaded to allow the HREC to easily identify the changes made. Please upload one tracked copy of each new version of a document.

Am I uploading as a new version Yes/No? Yes when the document you are submitting to the HREC already exists in the system e.g. a Study Protocol will always have a previous version.

No when you want to upload a new document that does not have a previous version already existing in the system. note: studies that have been migrated from a legacy system will have HREC approved documents but they may not yet be available to update in SAGE, in this case No should be selected.

Instructions to upload a new version

Instructions to upload a new document

List all documents that are being submitted for review

Upload as a new version	Document title/ Descriptor	Document Type	Upload file
<input type="radio"/> Yes <input checked="" type="radio"/> No	Fee Form	Fee Form	File Name: Fee Form.docx, Size: 11.87 kB
<input type="radio"/> Yes <input checked="" type="radio"/> No	Document 1	Study Protocol	File Name: Document 1.pdf, Size: 31.35 kB
<input type="radio"/> Yes <input checked="" type="radio"/> No	Additional Document 2	Clarification Letter	File Name: Document 2.pdf, Size: 31.66 kB

Maximum file size is 20.00 MB

Add Another

6. Once done, head to the declaration tab and hit submit.

Clicking the SUBMIT button below will submit your completed Amendment Notification form to the HREC for consideration.

General Amendment: Once this form is submitted you will be taken back to the forms page. Please note down the form ID as this will be needed in the site general amendment form.

A site general amendment form will be required to be submitted for each related site in SAGE. You are not required to resubmit any of the ethics forms in the site general amendment but you will be required to select this form ID to allow research offices to identify ethics approved documents.

Previous **Submit**

7. Once submitted, the status of the amendment form will be changed from “**Information Required**” to “**Information Provided**”. No further action is required.

TITLE	STATUS	OWNER	CREATED DATE	MODIFIED DATE	SUBMITTED DATE
061533 - Amendment Request	Approved	Lauren Cipagna	06/06/2022	06/06/2022	06/06/2022
061543 - Amendment Request	Information Provided	Sue Sie Ngwen	09/06/2022	09/06/2022	09/06/2022
061650 - Amendment Request	Information Provided	Janis Sukanto	11/08/2022	11/08/2022	11/08/2022

You DO NOT need to send another email to the RGU when responding to the comment unless you need further clarification. However, if you do not receive a response from RGU within 10 business days, please follow up at research.ethics@svhm.org.au