



SAGE – HOW TO SUBMIT A GOVERNANCE ONLY APPLICATION

All ethics and governance applications must be lodged via <u>SAGE</u>. Access SAGE here - <u>https://research.svhm.org.au/</u>

Please note that a completed HREA form is a requirement for a new Ethics Application; a completed SSA form is a requirement for a new Governance Application. For more information regarding the list of required documents, please refer to our website - <u>Human</u> <u>Research Ethics Committee - St Vincent's Hospital Melbourne</u>.

The HREA and SSA form must be completed on the ERM portal to meet the Victorian Department of Health reporting guidelines.

This guide provides a step-by-step instruction on how to submit your **Governance** applications to SVHM RGO when SVHM RGO is reviewing only the **Governance** application.

You will need an ethical approval from an Human Research Ethics Committee from an external institution accredited under the <u>National Mutual Acceptance (NMA) scheme</u>.

If you do not have an existing HREC approval, you will need to submit both <u>Ethics and</u> <u>Governance</u> applications, please refer to the full guide available on <u>our website</u>.

Steps to complete your governance application

- 1. Prepare documents required for governance application Prepare and Submit SSA Form on ERM
- 2. Lodge your governance application on SAGE Register a new project on SAGE to submit the documents

See documents required for Governance:

- New high-risk governance applications
- <u>New low-risk governance applications</u>

Abbreviations			
ERM	Ethics Review Manager		
SAGE	St Vincent's Applications for Governance and Ethics		
SSA	Site Specific Assessment		
HREA	Human Research Ethics Application		
HREC	Human Research Ethics Committee		
RGO	Research Governance Office		





Prepare and Submit SSA From on ERM

- i. If SVHM is the reviewing HREC or Ethics was approved by a non-SVHM HREC (Victorian HREC)
 - 1. Log on to ERM >
 - 2. Find your project >
 - 3. Click on **Project** to open the project tree, locate and complete the SSA form.



- ii. If the Ethics was approved by a non-SVHM HREC (Non-Victorian HREC)
 - 1. Log on to ERM >
 - 2. Create a project >
 - Enter Project Title, Jurisdiction (Victoria), Form (HREA) >
 - 4. Import XML derived from the original HREA and submit the form once completed.





5. Create Sub Form >



- Select Jurisdiction (Victoria), Select the Site-Specific Assessment (SSA) VIC sub-form >
- 7. Complete and submit the SSA form.

Create Sub	oform	\times
Select Jurisdiction		
Victoria	~	
Select the sub-form	that you would like to apply to	
Site Specific Asses	sment (SSA) VIC	
	Create	Close

For more guidance on ERM, please contact Infonetica helpdesk for assistance.

E-mail: <u>helpdesk@infonetica.net</u> Tel: +61 2 903 78 404





Registering your Governance application on SAGE

- Log on to <u>SAGE</u> (<u>See SAGE Login</u> instructions here) >
- 2. Select + New Form for Project Registration
- 3. Complete the Project Registration Form



The Project Registration form consists of 5 sections and takes approximately 5-10 minutes to complete, depending on the number of documents you upload. Click on each section below for more information.

Part A: Previous Ethics Application

- □ Part B: Project Details
- □ Part C: Research Site/s

Part D: Coordinating Principal Investigator

□ Part E: Upload Attachments

□<u>Submit</u>

Part A: Previous Ethics Application

- i. Select the "**Yes**" option for "*Do you have a Human Research Ethics Application* (*HREA*) form?"
- ii. Select "Ethics has been approved by a non-SVHM HREC" option for "What is the current status of your Ethics Application for this project?" >
- iii. Complete the details of the ethical approval for your study.

Do you have an Human Research Ethics Application (HREA) form?
Yes (recommended)
○ No
What is the current status of your Ethics Application for this project?
I am ready to submit the HREA to SVHM HREC
Ethics has been approved by a non-SVHM HREC
The following details are required to identify the previous ethics annihization the HBPC to which it was submitted and whether it was submitted under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health under the NMA arrangements which exist between a number of public health unde
status of that previous application may be requested.
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Part B: Project Details

i. Enter Project details which are outlined in the original HREA form including: project title and summary, research category, ethics review pathway, etc.





Part C: Research Site/s

- i. Select **Yes** if your study will be conducted at any of the following sites:
 - SVHM: St Vincent's Hospital Melbourne (Public)
 - **SVPH**: St Vincent's Private Hospital
 - Mercy Health

For more information on Governance requirements, please refer to the <u>SVHM Site-</u> <u>Specific Guidelines here</u>.

- 1. Enter site details and PI contact information >
- 2. Select the appropriate **Site Type** for the participating site.

For more information on different site types, please refer to the <u>Satellite, Recruitment &</u> <u>Service Site guidelines here</u>.

Depending on the selected site type, you will be required to submit the **ERM SSA form** or Head of Department (HoD) **Declaration of Support** in the Dropbox in Part C.

Have you completed your SSA Form on ERM? *	
• Yes No	
Please upload your SSA form from ERM here. Please attach all required docun next section.	nentations for governance authorisation in the
Drop files to attach, or brow	
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Please note that file format must be a .pdf file.

Part D: Coordinating Principal Investigator

i. Select **Yes**, if you are the Coordinating Principal Investigator for this study.

OR

- ii. Select No, if you are the Delegate registering the study >
- iii. Enter CPI SAGE email address

If the CPI does not have an account on SAGE, you can select Invite to Register.

Invite to	Register
Are you the	Coordinating Principal Investigator for this project?* @
O Yes	No No

Alternatively, you may send an email to <u>research.directorate@svha.org.au</u> to create an account for the CPI. Please provide the **Full name** and **Email address** of the CPI in your request.





Part E: Upload Attachments

- i. Submit all application documents related to your study. The full list of required documents can be found in the following links:
 - New high-risk governance applications
 - New low-risk governance applications
- ii. Please be advised that all documents submitted to ERM must also be submitted to SAGE.

Warning: DO NOT UPLOAD THE SAME DOCUMENT TWICE as this will prevent you from submitting the form. Please do not re-upload the **SSA or the letter of support**, if you have already uploaded this document in **Part C**.

Submit

Once the project registration is complete, the SSA and/or Declaration of Support form and all study documents will be sent to the Research Office. You are not required to send us your application documents via email.

Successful Project Registration

Upon successful submission of your project, a unique **PID** number will be generated. This identifier will be used for all related email correspondence.



Since this is a governance only application, you will be able to see your governance application with the "submitted" status. The ethics application has a unique **SSA** identifier.

IDENTIFIER	T	TITLE T	STATUS
2025/SSA00035		Governance only project - St Vincent's Hospital	Submitted

Under the **<u>Hierarchy</u>** tab, you will be able to see the SSA box being generated.

Hierarchy	History	
Q025/PIL Governance or	000051 Ily proj e ct	Covernance only proje

SSA= Site-Specific Assessment





If your project involves multiple sites at SVHM campus, for example SVHM and SVPH, then 2 separate SSA branches will be generated for each participating site.

For more details on the different status types, please refer to the <u>SAGE Status Dictionary</u> <u>here</u>.