

# SAGE – ETHICS & GOVERNANCE APPLICATION SUBMISSION GUIDE

## Guide to Submitting Ethics and Governance Applications to SVHM HREC/RGO

All research projects involving human participants or data require approval from the Human Research Ethics Committee (HREC). If your project will be conducted at any of the following sites, you will also need Site-Specific Assessment (SSA) approval for governance:

- St Vincent's Hospital Melbourne (SVHM) Public Hospital
- St Vincent's Private Hospital
- Mercy Health

### When to use this guide: Use this guide if you are:

- Seeking ethics approval for a **high-risk research project** at any of the above sites; or
- Seeking ethics approval for a **low-risk research project** conducted at **multiple** sites, including any of the above.

**Important:** You will need to submit an ethics application first to obtain HREC approval before submitting an SSA to obtain governance approval.

### All ethics and governance applications must be lodged via [SAGE](#).

Access SAGE here - <https://research.svhm.org.au/>

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 - [Human Research Ethics Committee - St Vincent's Hospital Melbourne](#).

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

## Steps to complete your ethics application for HREC review

- 1. Prepare documents required for an ethics application**  
[Prepare and Submit HREA Form on ERM](#)
- 2. Lodge your ethics application on SAGE**  
[Submit application documents and the HREA Form on SAGE via the Project Registration Form](#)

See other documents required for an Ethics Application:

- [New high-risk ethics applications](#)
- [New low-risk ethics applications](#)

## Steps to complete your governance application after receiving SVHM HREC approval

- 3. Prepare documents required for a governance application**
  - [Prepare and Complete the SSA Form on ERM](#)
- 4. Lodge your governance application on SAGE**  
[Submit application documents and the SSA Form via the SSA submission form](#)

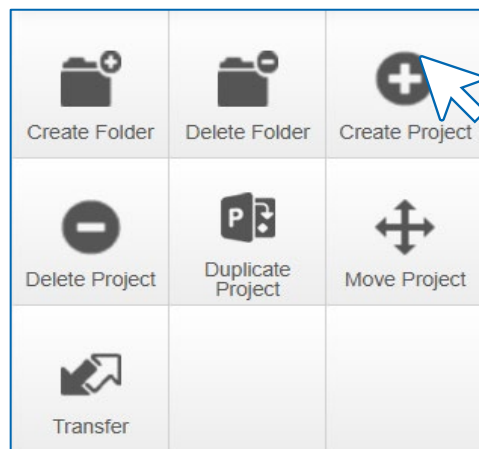
See other documents required for a Governance Application:

- [New high-risk governance applications](#)
- [New low-risk governance applications](#)

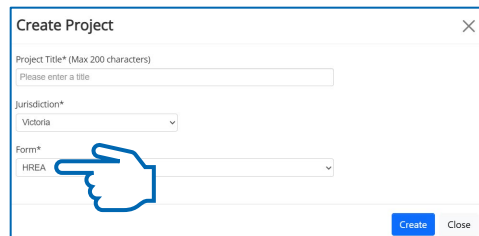
Abbreviations	
<b>ERM</b>	Ethics Review Manager
<b>NMA</b>	National Mutual Acceptance Scheme
<b>SAGE</b>	St Vincent's Applications for Governance and Ethics
<b>SSA</b>	Site Specific Assessment
<b>HREA</b>	Human Research Ethics Application
<b>HREC</b>	Human Research Ethics Committee
<b>RGO</b>	Research Governance Office

## Prepare and Submit HREA Form on ERM

1. Log on to ERM >
2. Create a project >



3. Enter Project Title, Jurisdiction (Victoria), Form (HREA) >



**Create Project**

Project Title\* (Max 200 characters)  
Please enter a title

Jurisdiction\*  
Victoria

Form\*  
HREA

Create Close

*Please note that HREA form is used for both **High-risk** and **Low-risk** studies.*

4. Complete and submit the HREA form.

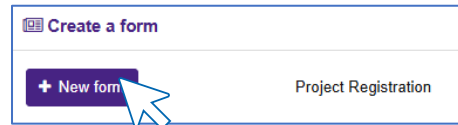
*For more guidance on ERM, please contact [Infonetica helpdesk](#) for assistance.*

*E-mail: [helpdesk@infonetica.net](mailto:helpdesk@infonetica.net) Tel: +61 2 903 78 404*

## Submitting your Ethics Application using the Project Registration Form

After gathering all documents required for an ethics application, you will need to upload them to SAGE.

1. Log on to [SAGE \(SAGE Login instructions\)](#) >
2. On the homepage, 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](#)
- [Submit](#) > [Successful Project Registration](#)

### Part A: Previous Ethics Application

- i. Select the **“Yes”** option for *“Do you have a Human Research Ethics Application (HREA) form?”*
- ii. Select the **“I am ready to submit the HREA to SVHM HREC”** option for *“What is the current status of your Ethics Application for this project?”* >  
*Note: If you have not completed the HREA form, please complete it on ERM first before submitting your ethics application.*
- iii. Drag and drop **ERM HREA** form >

### Part A: Previous Ethics Application

← Previous
Share Form with other Users

**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

Please upload pdf of ERM HREA application \*



Please note that the file format must be a .pdf file.

## 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. “Will this study be conducted at SVHM, SVPH or Mercy Health?”  
Select **Yes** if your study will be conducted at any of the following sites and select the correct option from the *Project Site* menu:
  - **SVHM**: St Vincent’s Hospital Melbourne (Public)
  - **SVPH**: St Vincent’s Private Hospital
  - **Mercy Health**

- ii. Enter the **Principal Investigator’s** email address and select the correct PI from the drop-down menu.

If you cannot find the PI’s username, please invite them to Register an account on SAGE, or contact [research.directorate@svha.org.au](mailto:research.directorate@svha.org.au) to create an account for them.

- iii. **Site Type:**  
If patients are being consented at SVHM, please select “**Full Site**”.  
If unsure, please select “**Full Site**”.

For more information on different site types, please refer to the [Satellite, Recruitment & Service Site guidelines here](#).

- iv. If a Full Site or Satellite Site is selected:  
the form will ask “**Have you completed your SSA Form on ERM?**”  
Select “**No**”.

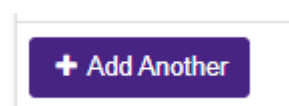
Since this is a high-risk or multisite study, you should NOT upload your SSA at this stage. You should only submit your SSA after receiving ethical approval. Submitting your SSA at this stage will result in an ineligible governance application.

If a Service Site or Recruitment Site is selected:  
the form will ask “**Have you received a Declaration of Support from the Head of Department to conduct this study?**”  
Select “**Yes**” to upload the supporting letter.

Please upload your **Letter of Support** here. Please attach all required documentations for governance authorisation in the next section.



- v. If another site under the SVHM Project Centre (SVHM, SVPH, or Mercy Health) is participating in the study, click “**+ Add Another**” to register it, and repeat the steps above.

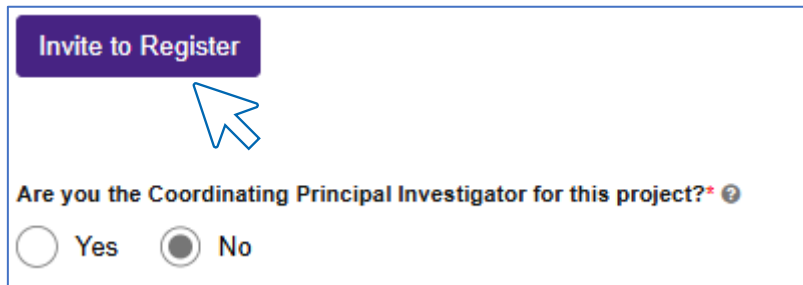


## Part D: Coordinating Principal Investigator

- 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



The screenshot shows a web form with a purple button labeled "Invite to Register" at the top. Below the button is a blue mouse cursor icon. Underneath is the question "Are you the Coordinating Principal Investigator for this project?\*" followed by a help icon. At the bottom of the question are two radio buttons: "Yes" (unselected) and "No" (selected).

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

Alternatively, you may send an email to [research.directorate@svha.org.au](mailto:research.directorate@svha.org.au) 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 ethics applications](#)
  - [New low-risk ethics applications](#)
- ii. Please be advised that all documents submitted to ERM must also be submitted to SAGE.

*Please do not re-upload the following documents in **Part F**:*

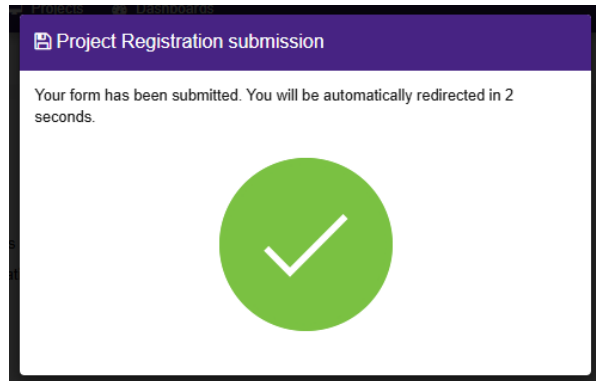
- **HREA**, if you have already included this form in **Part A**
- **SSA or Declaration of Support** if you have already included this form in **Part C**

## Submit

Once the project registration is complete, the HREA 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

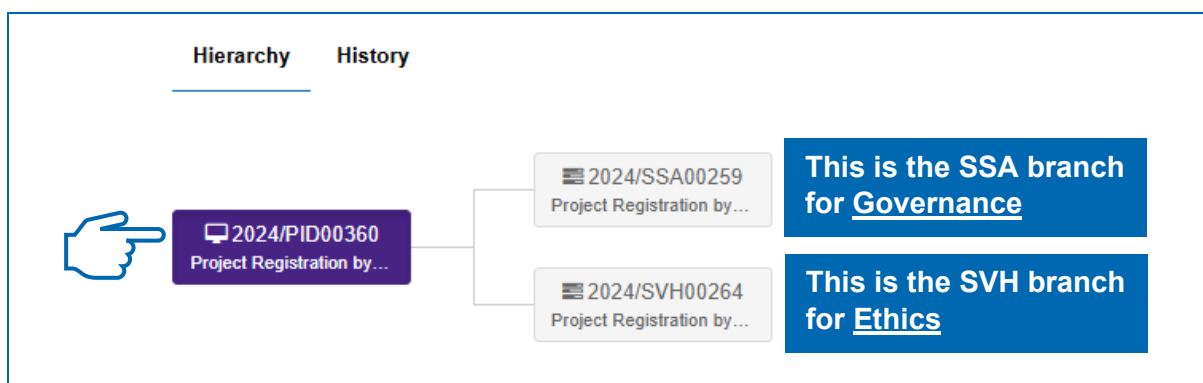
Upon successful submission of your project, a unique **PID** number will be generated. This identifier will be used for all related email correspondence.



Since this is both ethics and governance applications, the ethics application will have been submitted, while the governance application is still in progress.

IDENTIFIER	TITLE	STATUS
2025/SVH00044	High-Risk Ethics and Governance Submission - ...	Submitted
<a href="#">2025/SSA00037</a>	High-Risk Ethics and Governance Submission - ...	In Progress

Additionally, you will be able to view the project hierarchy, which includes the SVH and/or SSA application branches on the right-hand side of your screen.



*SVH = St Vincent's HREC; 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.

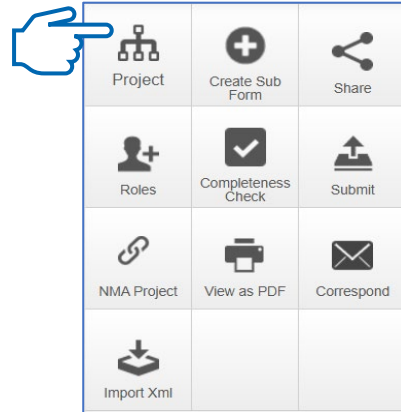
For more details on the different status types, please refer to the [SAGE Status Dictionary.s](#)

## Submitting a new governance application after receiving ethics approval from SVHM

### Preparing and Completing the SSA Form on ERM

i. If the Ethics Application was reviewed by a HREC within Victoria, including SVHM HREC.

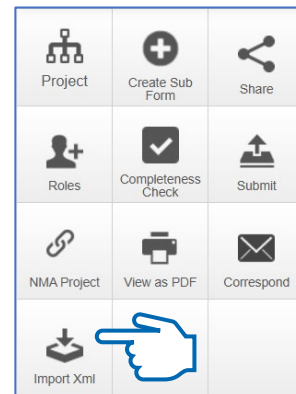
1. Log on to ERM >
2. Find your project >
3. Click on **Project** to open the project tree, locate and complete the SSA form.



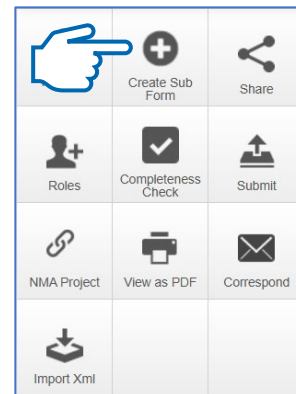
*If you are unable to locate your project, please contact the Sponsor or Study Team to share the project with you.*

ii. If the Ethics Application was reviewed by a HREC outside of Victoria.

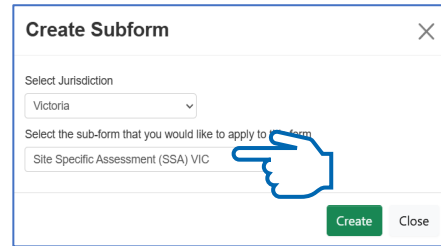
1. Log on to ERM >
2. Create a project >
3. Enter Project Title, Jurisdiction (Victoria), Form (HREA) >
4. Import XML derived from the original HREA and submit the form once completed.



5. Create Sub Form >



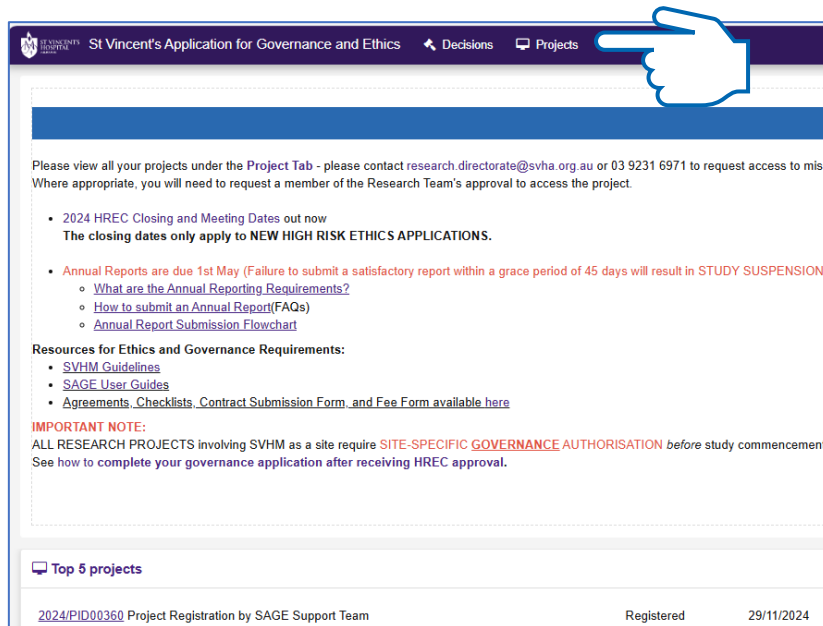
6. Select Jurisdiction (Victoria), Select the **Site-Specific Assessment (SSA) VIC** sub-form >
7. Complete and submit the SSA form.



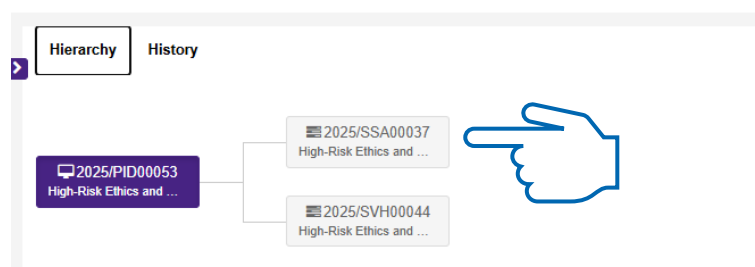
*For more guidance on ERM, please contact [Infonetica helpdesk](mailto:helpdesk@infonetica.net) for assistance.  
E-mail: [helpdesk@infonetica.net](mailto:helpdesk@infonetica.net) Tel: +61 2 903 78 404*

## Submitting your governance application using the SAGE SSA Summary Form

1. Log on to [SAGE](#) (See [SAGE Login instructions here](#)) >
2. Locate your project on the **Projects** tab or from the homepage under the Top 5 Projects

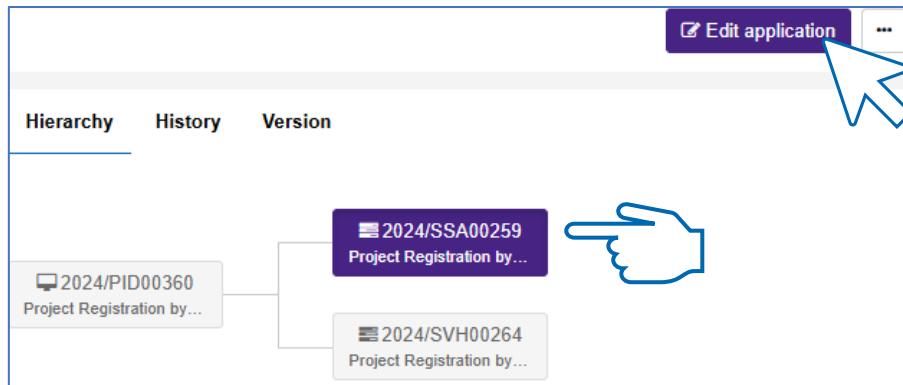


3. Click on the SSA branch as seen in the Project Hierarchy (located on the right-hand side of your screen) >





#### 4. Click “Edit application”



The **SSA Summary form** consists of 4 sections and takes approximately 3-5 minutes to complete, depending on the number of documents you upload. Click on each section below for more information.

- [Part A: Project Summary](#)
- [Part B: Site Team](#)
- [Part C: Department and Services](#)
- [Part D: Attachments – Site Specific Documents](#)
- [Submit](#)

#### Part A: Project Summary

- i. Select the reviewing HREC from the dropdown menu >
- ii. Indicate whether the study is **Single-** or **Multi-site** >
- iii. Follow the prompts and enter project details for the rest of Part A.

#### Part B: Site Team

- i. Fill in contact details for the PI at this site >
- ii. Upload PI CV and GCP in the file upload Dropbox >
- iii. Fill in contact details for the Study Coordinator/ Administration/ Contact Person

Principal Investigator

**2.2 Principal Investigator**

Email *	Name	Contact phone (mobile preferred) *
<input type="text" value="research.directorate@svha.org.au"/>	<input type="text" value="Research Directorate"/>	<input type="text" value="03 9231 6970"/>

Please attach Principal Investigator's CV and Good Clinical Practice (GCP) Certificate.  
Add additional rows to upload any other documents relating to the Principal Investigator. \*

Document type *	File upload *
<input type="text" value="CV - Curriculum Vitae"/>	<input type="text" value="Drop files to attach, or browse"/>
Document type *	File upload *
<input type="text" value="GCP"/>	<input type="text" value="Drop files to attach, or browse"/>

[+ Add document](#)

Contact person

**2.3 Administrative contact at this site**

Admin. Contact email (SAGE username) *	Admin. Contact Name
<input type="text" value="research.directorate@svha.org.au"/>	<input type="text" value="Research Directorate"/>

*If the PI or Contact Person does not have a SAGE account, please send an email to [research.directorate@svha.org.au](mailto:research.directorate@svha.org.au) to request for the account creation. Please provide the **Full name and Email address** of the PI or Contact Person in your request.*

## Part C: Department and Services

- i. **Add department** and select the appropriate supporting department for this study.

[+ Add department](#)

- **If SVHM (Public Hospital):**  
Select the relevant department(s) involved in the study. The Head of Department must be listed on the SSA form. You can request the Head of Department's electronic signature via ERM or obtain a letter of support. If you have a letter of support, please upload it here.
- **If SVPH (Private):**  
All studies conducted at SVPH must be signed off by the Chief Medical Officer as per institutional requirements. You do not need to request the Head of Department's signature.
- **If Mercy Health:**  
Select Mercy Health from the drop-down list and request a supporting letter from the appropriate institutional signatory.

## Part D: Attachments – Site Specific Documents

- i. Upload all the required Site-Specific Documents >
- a. [New high-risk governance applications](#)
  - b. [New low-risk governance applications](#)

Attachments – Site Specific Documents [Preview](#) [Save](#) [Next](#)

[Previous](#) [Next](#)

If there are any other SSA supporting documents (in addition to the documents already uploaded within this SSA) please attach below.  
Do not upload ethics supporting documents. Once your SSA is submitted, the site RGO can access the associated ethics documents from their research office SAGE account.

Document Type *	Document Descriptor *	
Fee Form	SVHM Fee Form	Drop files to attach, or <a href="#">browse</a>
<small>Maximum file size is 40.00 MB</small>		

[+ Add Another](#)

*Please note the following:*

- *Only site-specific documents need to be submitted in this section. Supporting documents submitted for the initial ethics approval are already stored in the system.*
- *When St Vincent's Hospital Melbourne (SVHM) serves as the lead Human Research Ethics Committee (HREC), the governance fee is waived for the initial submission to SVHM, provided it is submitted within three months of receiving ethical approval.*

*Submissions made outside of the three-month time frame will incur a new governance application cost.*

## Submit

[Complete SSA](#)

Once the SSA summary form has been submitted, the SSA form and all study documents will be sent to the Research Office. **You are not required to send us your application documents via email.**