SUBMITTING A CONCURRENT ETHICS AND GOVERNANCE APPLICATION ON SAGE

You can submit the ethics and governance application concurrently if it is a low-risk ethics application for a single-site project where St Vincent's Hospital Melbourne is the only participating site.

This guide provides a step-by-step instruction on how to submit your application to obtain concurrent Ethics and Governance Approval to SVHM HREC/RGO.

If your study is a High-risk or multisite study, you will need to submit your governance application separately after obtaining HREC approval. Please visit our website to check if your study qualifies for review under the low-risk ethics pathway.

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 and governance application concurrently

1. **Preparing documents required both ethics and governance application**
Prepare and Submit HREA Form on ERM

2. **Lodge your application on SAGE**
Register a new project on SAGE to submit the ethics and governance application and documents

See documents required for a low-risk ethics and governance application
The SSA form is not required for a single-site low-risk study where SVHM is the only participating site.
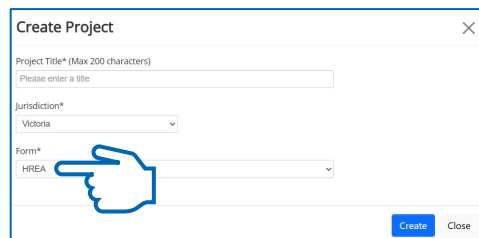
Abbreviations	
ERM	Ethics Review Manager
SAGE	St Vincent's Applications for Governance and Ethics
SSA	Site Specific Assessment
HREA	Human Research Ethics Application
HREC	Human Research Ethics Committee
LNR	Low or Negligible Risk
SSLNR	Single-Site Low or Negligible Risk
RGO	Research Governance Office

Prepare and Submit HREA Form on ERM

1. Log on to ERM >
2. Create a project >
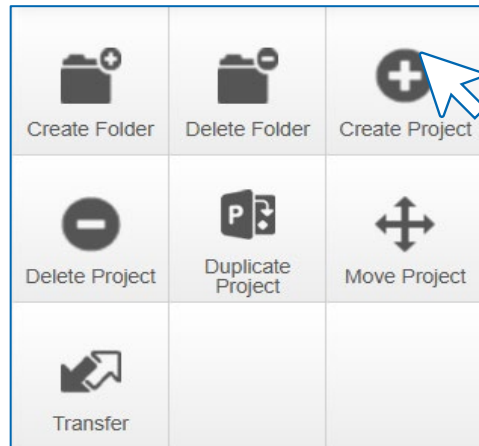
3. Enter Project Title, Jurisdiction (Victoria), Form (HREA) >

*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 **Tel**: +61 2 903 78 404*

You do not need a separate SSA form if your project is eligible for a low-risk ethics review pathway where SVHM is the only participating site.

Submitting your Ethics Application to SVHM HREC

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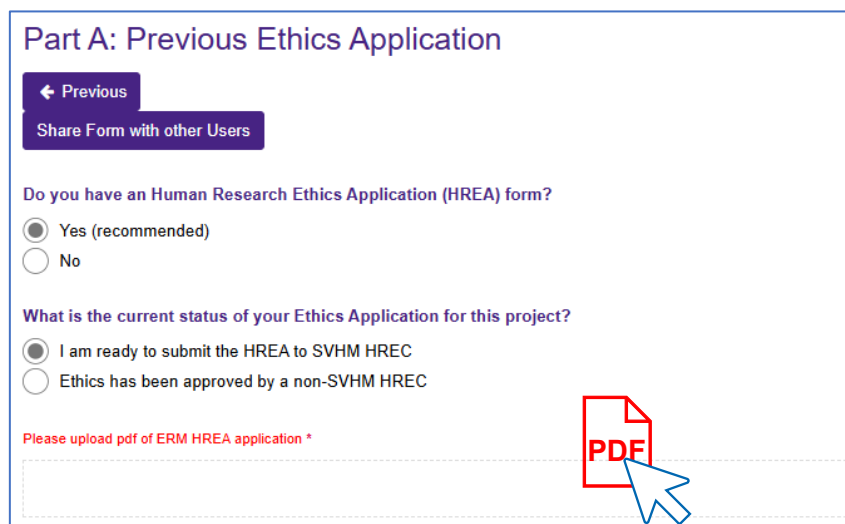3. Complete the Project Registration form
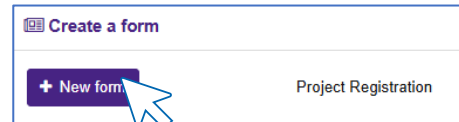
The Project Registration form consists of 5 sections and takes approximately 5-10 minutes to complete, depending on the number of documents you upload. Click on each section below for more information.

☐ Part A: Previous Ethics Application
☐ Part B: Project Details
☐ Part C: Research Site/s
☐ Part D: Coordinating Principal Investigator
☐ Part E: Upload Attachments
☐ Submit

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 >

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.

ii.   For the <u>Ethics Review Pathway</u>, please select **"Low or Negligible Risk (LNR)"** from the dropdown menu.

Please visit our <u>website</u> to check if your study qualifies for review under the low-risk ethics pathway.

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.   "Is this a single- or multi-site study?"
Select "**Single-site**".
If this is a multi-site study, please do not submit the SSA at this stage. Please follow the guide for ethics and governance submission for high-risk or multisite study.

iii.   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 to create an account for them. Please provide the PI's full name and email address.

iv.   **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*.

v.   If this is a single-site low-risk application where SVHM is the ONLY participating site, you can submit Head of Department (HoD) **Declaration of Support** in the Dropbox in Part C.

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

If your project is any of the following, you will need to submit a separate governance application AFTER obtaining the ethical approval:

- High-Risk ethics application, or
- Multisite study where SVHM is one of the participating sites.

In this case, select **High Risk (HREC) Ethics Review Pathway** in Part B, and Select "**No**" for the "**Have you completed your SSA Form on ERM**" question in Part C of the Project Registration Form.

> **Have you completed your SSA Form on ERM? ***
>
> ◯ Yes ⦿ No
>
> Please complete your **SSA Form on ERM**.
> You may upload the completed SSA form after completing your project registration.

Please see our website for guidance to submit your governance application after receiving ethical approval from SVHM HREC.
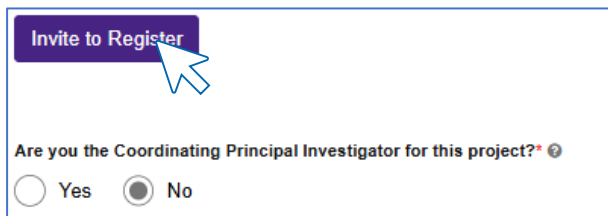
Part D: Coordinating Principal Investigator

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?*** ❓
> ◯ Yes ⦿ No

*Alternatively, you may send an email to 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:
        o   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.
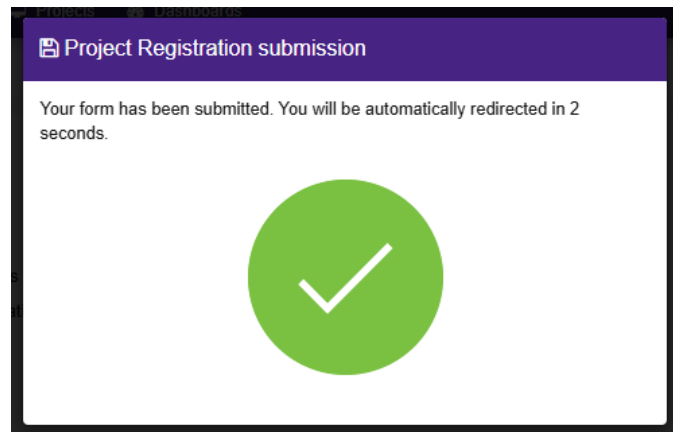
Additionally, you will be able to find two applications with the following unique identifiers under the **Hierarchy** tab on the right side of the screen.

1. The **SSA** Identifier: This is your governance application (SSA= Site-Specific Application)
2. The **SVH** Identifier: This is your ethics application (SVH = St Vincent's HREC)
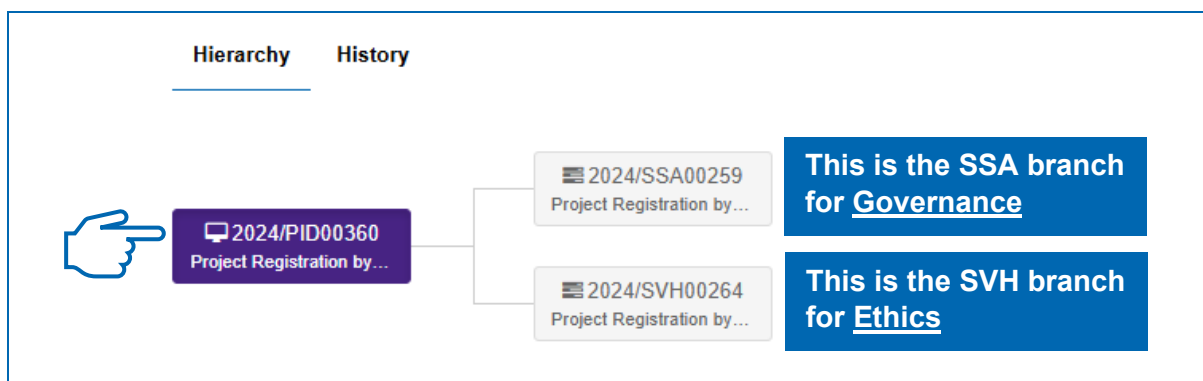
To view your application status, click on the PID in the hierarchy as shown in the image above. This will bring up the application viewer for your project.

For more details on the different status types, please refer to the SAGE Status Dictionary.