

SAGE – HOW TO SUBMIT AN ETHICS ONLY APPLICATION

This guide provides a step-by-step instruction on how to submit your **Ethics** applications to SVHM HREC when SVHM HREC is reviewing only the **Ethics** application. This means that your project does not involve any of the following sites:

- St Vincent's Hospital Melbourne
- St Vincent's Private Hospital
- Mercy Health

If your study involves any of the above sites, you will need to submit both <u>Ethics and Governance</u> applications, please refer to the full guide available on our <u>website</u>.

All ethics and governance applications must be lodged via <u>SAGE</u>.

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

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 using the Project Registration
Form

See other documents required for an Ethics Application:

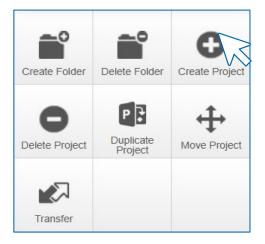
- New high-risk ethics applications
- New low-risk ethics applications

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 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 <u>Infonetica helpdesk for assistance</u>.

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





Submitting your Ethics application to SVHM HREC using the Project Registration Form

- Log on to <u>SAGE</u> (<u>See SAGE Login</u> instructions here) >
- 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 >



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

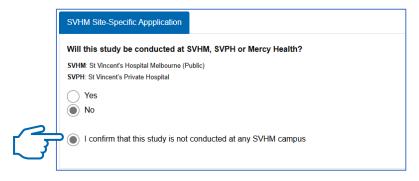
Part B: Project Details

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. Select **No** as SVHM is only reviewing the Ethics application of this study. This indicates that you are not applying for Governance at any of the sites mentioned above
- ii. Confirm that that study is not conducted at any SVHM campus (SVHM/ SVPH/ Mercy Health).



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.



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 ethics applications
 - New low-risk ethics 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 **HREA**, if you have already uploaded this document in **Part A**

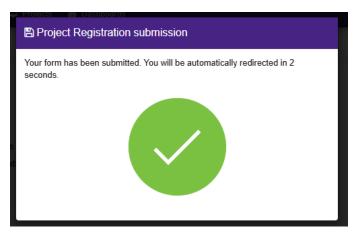


Submit

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 an ethics only application, you will be able to see your ethics application with the "submitted" status. The ethics application has a unique **SVH** identifier.



Under the Hierachy tab on the right, you will be able to see the SVH box being generated.



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