

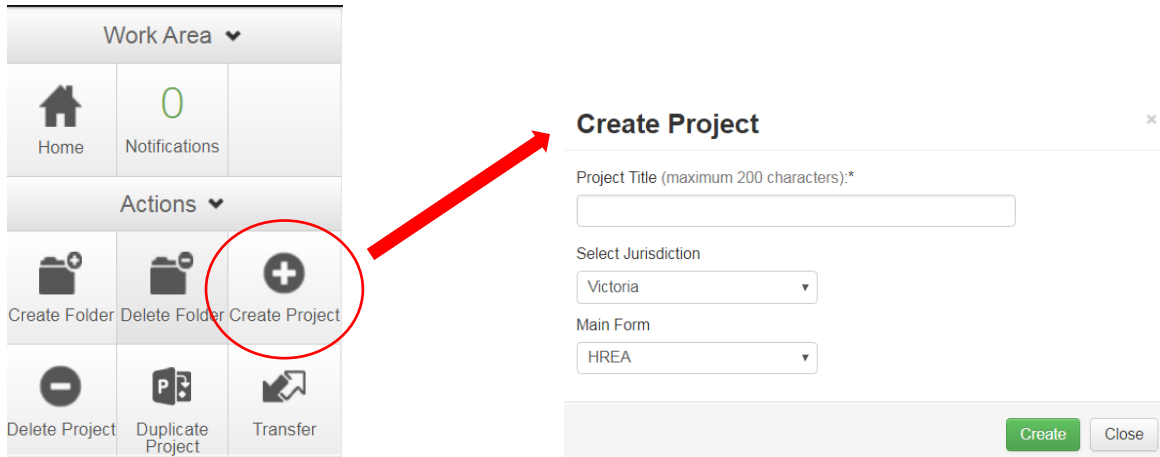


How do I complete and submit my application through ERM?

- Log in to your ERM account or for first time users create an account








<https://au.forms.ethicalreviewmanager.com/>

- Use the action menu on the left hand side of the screen to create a new project.



- Enter project title, select jurisdiction and select HREA form. Click Create.

Actions menu buttons

-  **Project** Project overview
-  **Share** Share the application with other project members if required
-  **Completeness Check** Check what is left to be completed in the form
-  **Submit** Submit form to Office for Research
-  **NMA Project** For project submitted under National Mutual Acceptance
-  **Print** Creates a PDF of your application form
-  **Correspond** Email the Office for Research through ERM about your application (once project has been submitted)



ERM GUIDANCE FOR HREA APPLICATIONS

- Complete your HREA form.

Project Tree ▼

- HREA Test 1
- HREA

Form Status	Review Reference	Application Type	Date Modified	NMA
Not Submitted	N/A	N/A	05/09/2018 09:48	Project is not for NMA

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HREA

Section

ERM Module

HREA Introduction

Show Inactive Sections

Questions

ERM Filter Questions

Introduction | HREC Directory

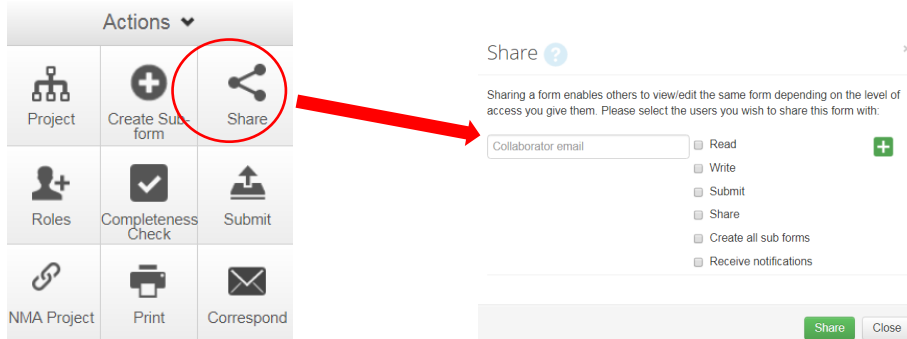
Click on 'ERM Filter Questions' to start completing form

Tips for completing the HREA form:

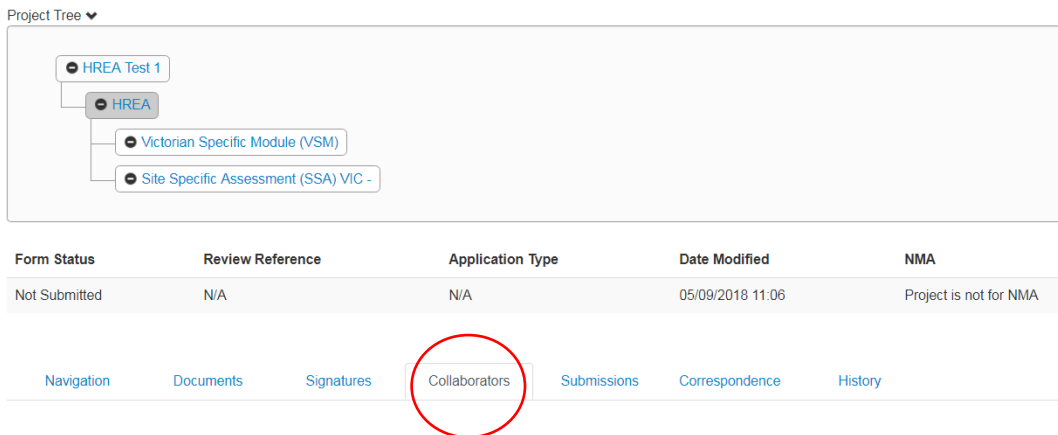
- The Office for Research does not use a local reference number. Leave blank.
- For most HREA applications being reviewed by the PH HREC, the major sponsor of the project is 'Institution' and the Australian Sponsor is Peninsula Health.
- If this is your first time completing a form in ERM - type in contact details and click 'add to contacts' to save to your address book for future reference. *Note you cannot submit the form if you leave any of the contacts fields blank.*
- Question 1.6 – Answer 'In kind support from department' if your project is an internal non-sponsored project.
- Question 1.8 – Please note a study is considered complete when no further contact with participants/data source is foreseen, including data analysis and reporting period. Please factor this into the anticipated duration of your project.
- Question 1.9.11 - Please tick no to this question. All members of the research team must sign the application.
- Question 3.14 – Contact the Office for Research regarding Peninsula Health requirements for information/data storage, access, archiving and/or destruction.
- Question 4.1 – Peninsula Health has protocol templates available and advises PH researchers to utilise these templates.
- Question 4.5 – Select greater than low risk review pathway if you are submitting the HREA to Peninsula Health HREC. Low and Negligible risk projects are submitted using the LNR VIC Form. You should have already received a Low Risk Confirmation if your study is to be reviewed as Low Risk.
- Upload supporting documents as required for your project. Use the forms and templates available from our website where available.
- Investigator Team Declarations - The Office for Research does not accept one member signing on behalf of the research team. All members listed on the HREA must sign the form.



How do I share the project with other researchers on this project?



- If you wish to share the application in question, click on "Share" within the Action menu and enter the email address (which matches the ERM account) of the person you wish to share the form with. You will need to specify what level of access you would like the person to have. This can be modified at any time within the application 'Collaborators' tab.
- All collaborators must have an ERM account for this function to work.
- It is advisable to have at least one other member of the team with (as a minimum) viewing access to the application.



Obtaining electronic signatures

- The PI and Associate Investigators are required to sign the HREA form.
- This will mean they will need to have their own ERM account in order to sign the document. You will need to click 'request signature' button to obtain the necessary signatures. You will need to enter the email address that matches the ERM account of the person you are requesting to have sign the form.
- **Please note: Any modifications or updates to your form will invalidate any signatures you have obtained. This will require you to request signatures again.**

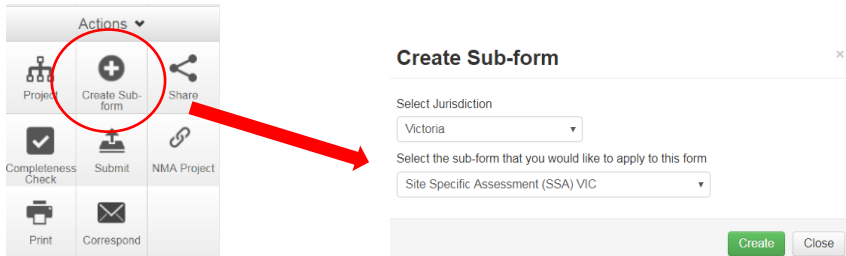
Submitting your application

- Submit your application only after you have received **all signatures**.
- After you submit through ERM you will receive instructions on how to track the progress of your application.



Completing the SSA

- The SSA is a sub-form of the HREA application.
- Use the action menu on the left hand side of the screen to create a new sub-form.



- Complete your SSA form.

Tips for completing the SSA form:

- For single-site projects being reviewed by PH HREC, only include the PI details in the SSA as all other investigator details should be included in the HREA already. Load this info from your address book to save re-typing.
- Question 2.1 – Tick 'no' to this question as per the above.
- You are not required to upload documents to the SSA that have already been uploaded to the HREA.
- Particularly for single-site projects there will be some duplicate information required in the SSA as the HREA. We are exploring options to minimise this duplication.
- Question 3.1 & 3.2 – Include the same dates/timeframe provided in the HREA.
- Question 3.3 - Ensure you have included all supporting departments that will be required to sign the application
- Question 3.5 – The Peninsula Health research policies are available via Prompt. Contact the Office for Research if you are unsure which policies apply to your project.
- Question 3.1 – Most single-site HREA applications will not require a research agreement. If you tick 'no' to 3.1 you will be asked to provide an explanation. For most projects write 'not required' to 3.1(c).
- Question 5.1 - Most single-site non-sponsored projects will have in kind support from a department. Include Peninsula Health's details as the Sponsor Contact if this is the case with your project.
- If your answered Question 5.1 as directed above, Answer the questions below as follows:
 - Questions 5.2 as 'None', 5.2(a) as 'not required'
 - Questions 5.3 as 'None', 5.3(a) as 'not required'
 - Questions 5.4 as 'No', 5.4(a) as 'not required'
- Contact the Office for Research if you are unsure how to answer any questions within the SSA.

Obtaining electronic signatures

- The PI and the Head of Department and Head/s of Supporting Departments must electronically sign the form before the SSA is submitted. This will mean they will need to have their own ERM account in order to sign the document. Use the 'request signature' button to obtain the required signatures. You will need to enter the email address that matches the ERM account of the person you are requesting to have sign the form.



ERM GUIDANCE FOR HREA APPLICATIONS

- **Please note: Any modifications or updates to your form will invalidate any signatures you have obtained. This will require you to request signatures again.**

Submitting your application

- Submit your application only after you have received all electronic signatures on the form.
- After you submit through ERM you will receive instructions on how to track the progress of your application.

After submission of your application

- Check the status of your application via the History or Submission tab.

Project Tree ▾

- HREA Test 1
 - HREA
 - Victorian Specific Module (VSM)
 - Site Specific Assessment (SSA) VIC - Peninsula Health

Form Status	Review Reference	Application Type	Date Modified	NMA
Not Submitted	N/A	N/A	05/09/2018 12:00	Project is not for NMA

Navigation | Documents | Signatures | Collaborators | **Submissions** | Correspondence | **History**

- If the Office for Research have a query regarding your application you will receive correspondence through ERM. This will be visible via the Notifications button in the main work area.

Work Area ▾

- Home
- 1** Notifications
- Correspond

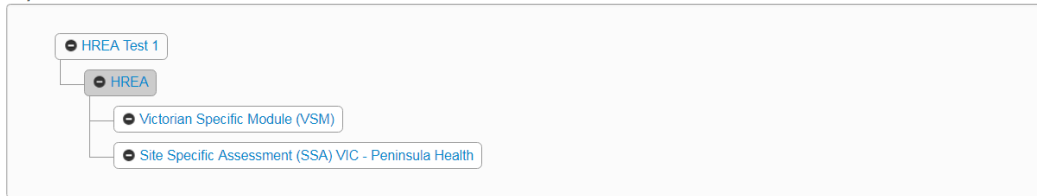
You can respond back to the Office for Research via ERM using the correspond button.

- All feedback regarding the project is viewable via the application Correspondence tab.



ERM GUIDANCE FOR HREA APPLICATIONS

Project Tree ▾



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- The approval letter will be sent as correspondence through ERM and will display in the notifications area also. It will be an attachment to the correspondence message and is downloadable. It will remain viewable via the Correspondence tab of your application (see above).

After project approval

- You can commence your project once you have received the approval letter.
- All post approval submissions such as amendments, safety reports and progress/final reports are to be submitted via ERM (see below). All forms are created as a sub-form of the HREA application (unless this is a multi-site project approved through an external HREC where the sub-forms are created from the SSA).
- Annual progress reports are due by the September HREC meeting agenda closure deadline each year. The reporting period for progress reports is 1 July – 30 June each year.
- Email any questions about your project to the Office for Research via the project Correspondence tab.
- Contact the Office for Research if you need guidance or support.