

# ERM – User guide

The Royal Children's Hospital, Melbourne

Compiled by Katherine Lieschke  
Ethics Submissions Officer, Melbourne Children's Trials Centre

With thanks to the Mater Research *Ethics Review Manager (ERM) User Guide for researchers*

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## Logging in to ERM

You may **already have an ERM account**. If you owned an application that was submitted prior to July 2018, then you should be able to login with the same details as your AU Online Forms account.

### To create an account:

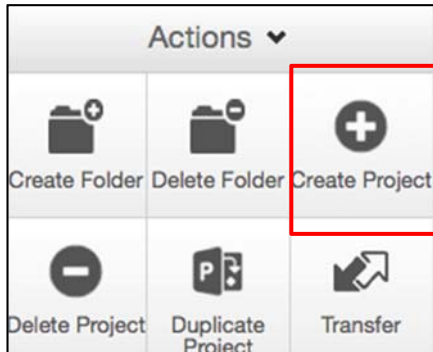
1. Click on "New User".
2. Fill in the applicable information (you can skip fields that are not relevant to you), and agree to the Terms and Conditions.

NOTE: Password must be 8+ characters long, contain both upper and lowercase characters and contain at least 1 number.

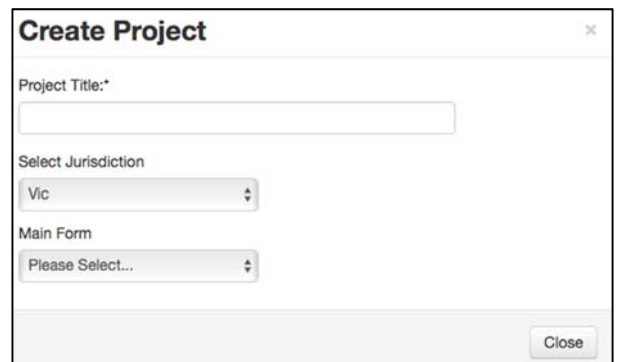
3. Click "Register" and an activation email will be sent to the entered address.
4. Access email and click the activation link provided.
5. Return to the login page and click "Log in".

## Creating a new project

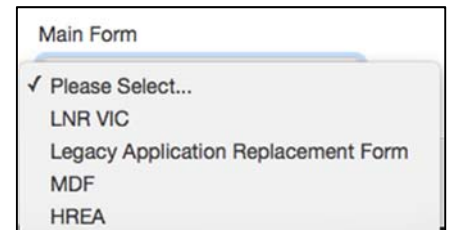
1. From the ERM Home Page, click on “Create Project”.



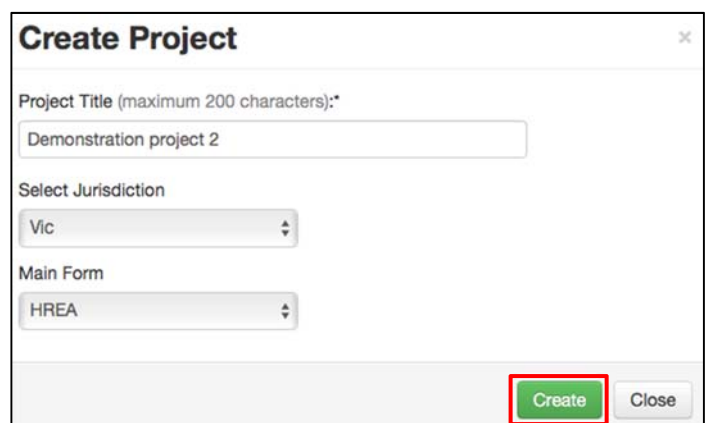
2. Fill in the project title.
3. Select the jurisdiction (Victoria).

A screenshot of the 'Create Project' dialog box. It has a title bar with 'Create Project' and a close button. The form contains: a 'Project Title:\*' text input field; a 'Select Jurisdiction' dropdown menu with 'Vic' selected; and a 'Main Form' dropdown menu with 'Please Select...' selected. A 'Close' button is located at the bottom right.

4. Select the Main Form from the list of options.  
The Main form is the central application form for the project.



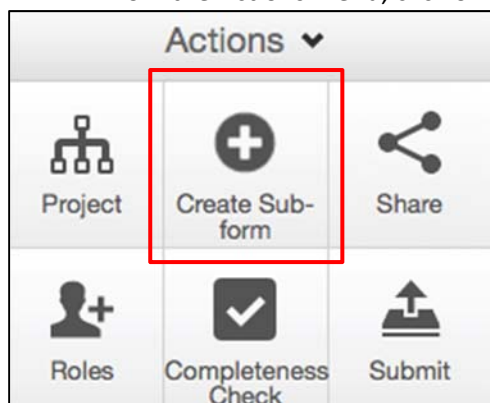
5. Click the “Create” button.
6. The new project will open.

A screenshot of the 'Create Project' dialog box. The 'Project Title' field now contains the text 'Demonstration project 2'. The 'Select Jurisdiction' dropdown menu still shows 'Vic', but the 'Main Form' dropdown menu now shows 'HREA' selected. The 'Create' button at the bottom right is highlighted with a red rectangular box.

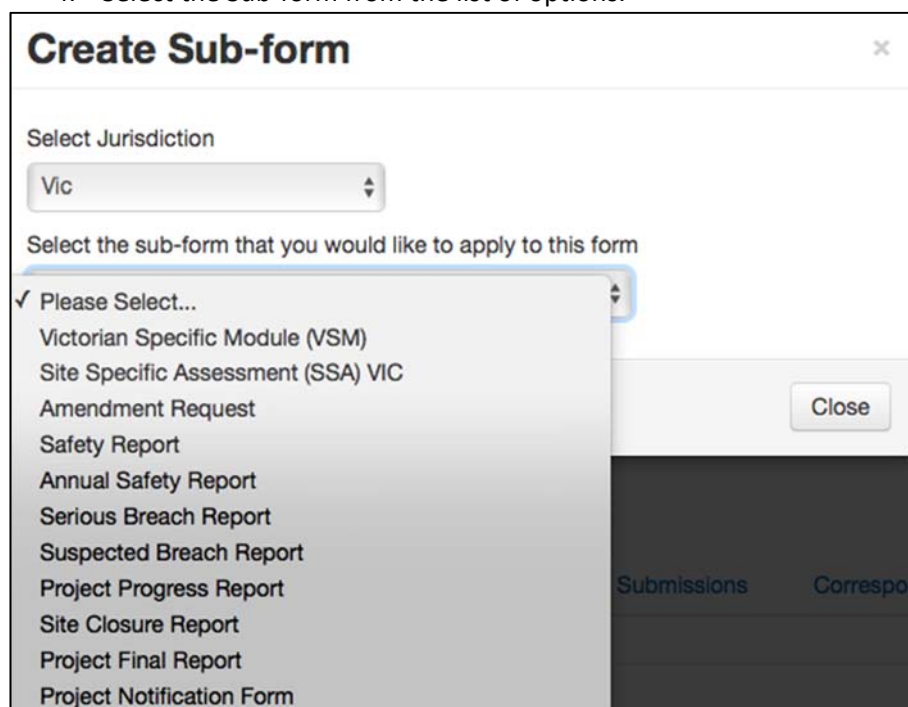
## Creating sub-forms (VSM, SSA, post-approval forms)

Sub forms are the forms associated with an application that are not the main form.

1. Open the project you want to make a sub-form for.
2. From the Actions menu, click on "Create Sub-form".

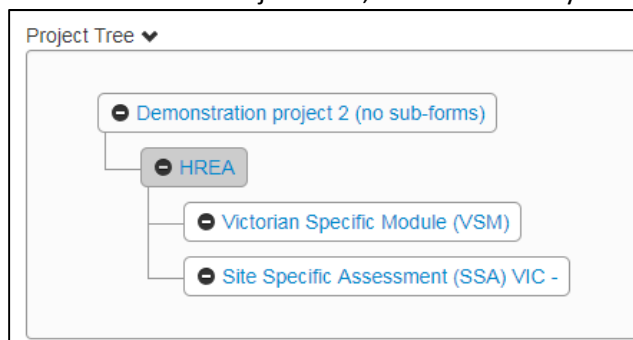


3. Select the jurisdiction (Victoria).
4. Select the Sub-form from the list of options.

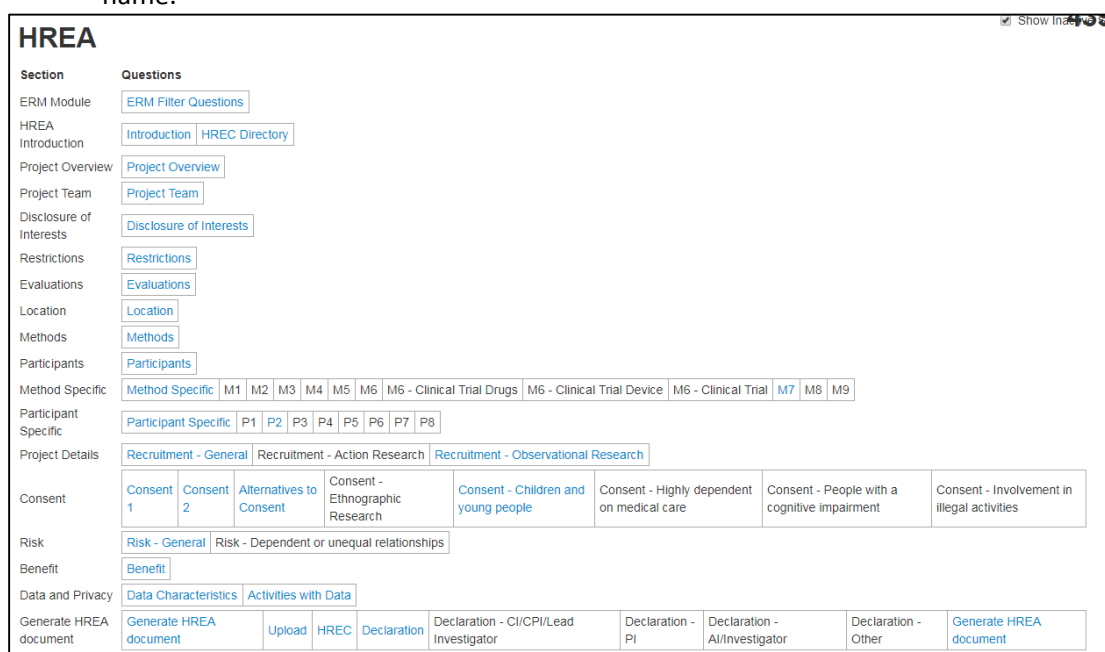


## Filling in forms

1. From the Project Tree, select the form you want to work on.



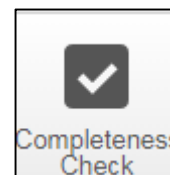
2. You can select specific sections of the form to navigate to by clicking on the section name.



**HREA** Show Instructions

Section	Questions
ERM Module	<a href="#">ERM Filter Questions</a>
HREA	<a href="#">Introduction</a> <a href="#">HREC Directory</a>
Introduction	
Project Overview	<a href="#">Project Overview</a>
Project Team	<a href="#">Project Team</a>
Disclosure of Interests	<a href="#">Disclosure of Interests</a>
Restrictions	<a href="#">Restrictions</a>
Evaluations	<a href="#">Evaluations</a>
Location	<a href="#">Location</a>
Methods	<a href="#">Methods</a>
Participants	<a href="#">Participants</a>
Method Specific	<a href="#">Method Specific</a> M1 M2 M3 M4 M5 M6 M6 - Clinical Trial Drugs M6 - Clinical Trial Device M6 - Clinical Trial M7 M8 M9
Participant Specific	<a href="#">Participant Specific</a> P1 P2 P3 P4 P5 P6 P7 P8
Project Details	<a href="#">Recruitment - General</a> <a href="#">Recruitment - Action Research</a> <a href="#">Recruitment - Observational Research</a>
Consent	<a href="#">Consent 1</a> <a href="#">Consent 2</a> <a href="#">Alternatives to Consent</a> <a href="#">Consent - Ethnographic Research</a> <a href="#">Consent - Children and young people</a> <a href="#">Consent - Highly dependent on medical care</a> <a href="#">Consent - People with a cognitive impairment</a> <a href="#">Consent - Involvement in illegal activities</a>
Risk	<a href="#">Risk - General</a> <a href="#">Risk - Dependent or unequal relationships</a>
Benefit	<a href="#">Benefit</a>
Data and Privacy	<a href="#">Data Characteristics</a> <a href="#">Activities with Data</a>
Generate HREA document	<a href="#">Generate HREA document</a> <a href="#">Upload</a> <a href="#">HREC</a> <a href="#">Declaration</a> <a href="#">Declaration - CI/CPH/Lead Investigator</a> <a href="#">Declaration - PI</a> <a href="#">Declaration - AI/Investigator</a> <a href="#">Declaration - Other</a> <a href="#">Generate HREA document</a>

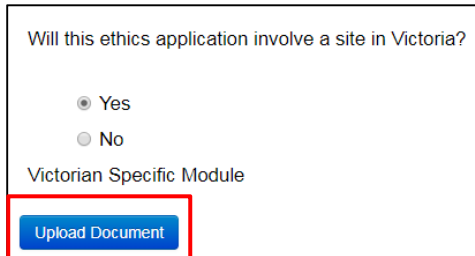
3. Complete the questions in the forms.
4. You can use the “Previous” and “Next” buttons to move through the form.  
The Navigate button will take you back to the list of questions.
5. To check if the form is complete, use the “Completeness Check” button on the Actions menu. This will bring up a list of outstanding or incomplete questions that you can navigate to.
6. You should download a PDF of the completed form by clicking [Print](#).





## The VSM

1. To create the VSM, follow the instructions in the [Creating sub-forms](#) section.
2. Enter information into the VSM and use the completeness check function to check that the form is complete. See the [Filling in forms](#) section for more information.
3. [Print](#) the VSM, and save it as a PDF.
4. Return to the HREA.  
You can do this via the Project Tree.
5. In the HREA Form, navigate to the section “ERM Filter Questions”.
6. Upload the PDF of the VSM where indicated. For more information, see the [Attaching Documents](#) section.

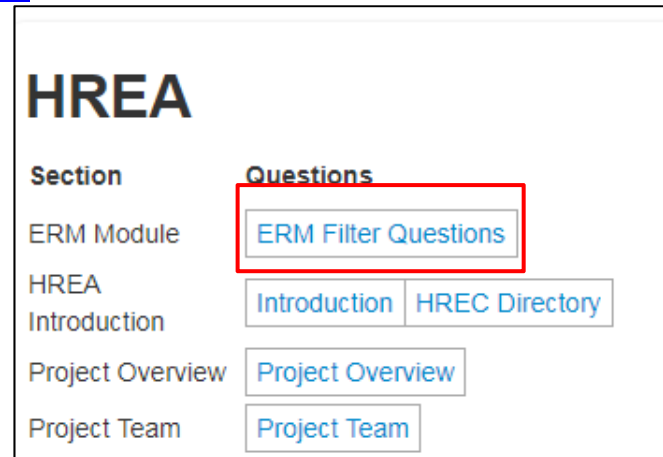


Will this ethics application involve a site in Victoria?

Yes  
 No

Victorian Specific Module

[Upload Document](#)



### HREA

Section	Questions
ERM Module	<a href="#">ERM Filter Questions</a>
HREA	<a href="#">Introduction</a> <a href="#">HREC Directory</a>
Introduction	
Project Overview	<a href="#">Project Overview</a>
Project Team	<a href="#">Project Team</a>

7. After the HREA has been submitted, submit the VSM. More information can be found in [Submitting forms](#).

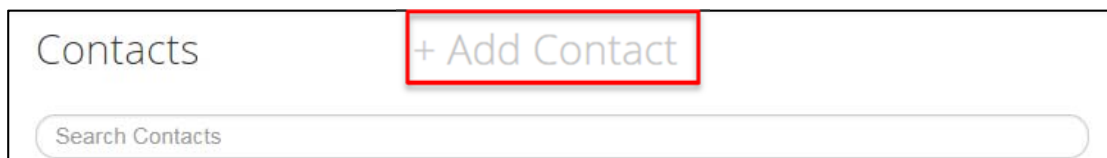
## Researcher Contact details

### Contacts Page

The contacts page displays all people you have listed as a contact.

To add a contact:

1. Click on “+ Add Contact”.

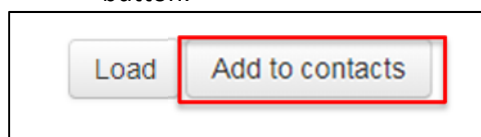


2. Enter details for the person.
3. Press “Save”.

### Saving a contact

You can save a contact from a form so that you do not need to repeatedly enter details for researchers.

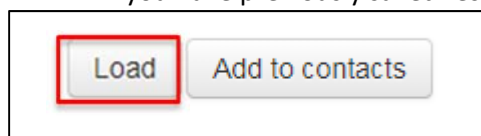
1. When you have entered details for a researcher, click on the “Add to contacts” button.



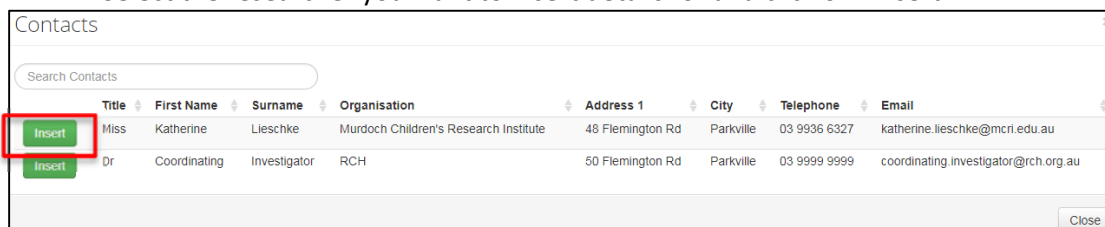
2. The researcher will be saved to your contacts.

### Loading researcher contact details

1. If you have previously saved researcher details, click on the “Load” button.



2. Select the researcher you want to insert details for and click on “Insert”.

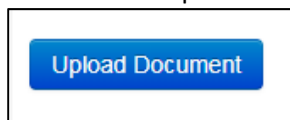


3. The contact details will be loaded into the form.


## Attaching documents

Documents need to be uploaded in various places on the forms. You can upload them as you go or go back later and upload them. Use the completeness check function (see [Filling in forms](#)) to check that all forms have been uploaded.

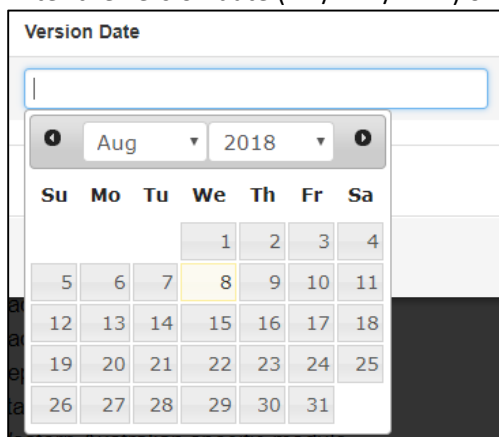
1. Click on the “Upload Document” button.



2. Click on the “Browse” button.



3. Select the appropriate document from your computer and click “Open”.
4. Enter the version date (DD/MM/YYYY) or select from the drop-down calendar.



5. Enter the version number.
6. Click “Upload”.

## Viewing Attached Documents

Different documents can be attached to different forms. For example, site-specific ICFs should be attached to the SSA, while the master form is attached to the HREA.

To view form documents simply click the Documents tab. This tab displays a table with all the form documents.

## Multi-site (NMA) applications

For a multisite application that will be submitted as part of the NMA scheme, this needs to be indicated as follows.

1. Navigate to the section of the HREA labelled "HREC".
2. In question 4.6, select yes.

**Q4.6 Will this application be reviewed under the National Mutual Acceptance scheme?**

- Yes  
 No











3. Return to the navigate page.
4. Form the Actions menu, select "NMA Project".
5. Select "Project is NMA" from the drop-down menu.

### NMA Project

Mark this project as NMA if it is to be reviewed under the National Mutual Acceptance scheme.

Project is NMA

6. Press Save.

Actions ▾		
 Project	 Create Sub-form	 Share
 Roles	 Completeness Check	 Submit
 NMA Project	 Print	 Correspond
 Import Xml		

## Signatures

When a Form is complete, you need to request signatures from the appropriate people. There are three forms of signatures in ERM, electronic/digital signature, uploading other evidence, and print to sign.

To indicate who will be signing the form, you will need to check the boxes to indicate which roles will be signing the application. This will generate declarations for these roles.

For all non-HREA forms, all signatures must be electronic/digital.

### Electronic/digital signatures

1. On the declaration page, click “Request Signature”.
2. Enter the email address of the person who will be signing the application.
3. To let the person know what they are being requested to do, add a message.
4. Use the “Request” button to send the request to the investigator.
5. If an additional person needs to sign the application in this role, click the “Add another signature” button.

[Add Another Signature](#)



To view form Signatures/Requests simply click the Signatures tab. This tab will display both the signatures that have been done, along with the requested signatures yet to be completed. In the request section there is a Cancel button that will cancel a signature request.

Signatures need to be done before the form is submitted. After submission, the form is locked for review. Electronic signatures are not possible while the form is locked. Submitting the form invalidates outstanding requests for signatures.

### Upload Other Evidence

If using this option, you need to upload a document containing evidence of the approval. This could include an email or some other form of evidence that the investigator approves the trial.

### **Wet Ink for Printing**

Choosing this option will generate a signature line that can be signed after printing.

This option can be used if signatures will not be available prior to submission of the HREA.

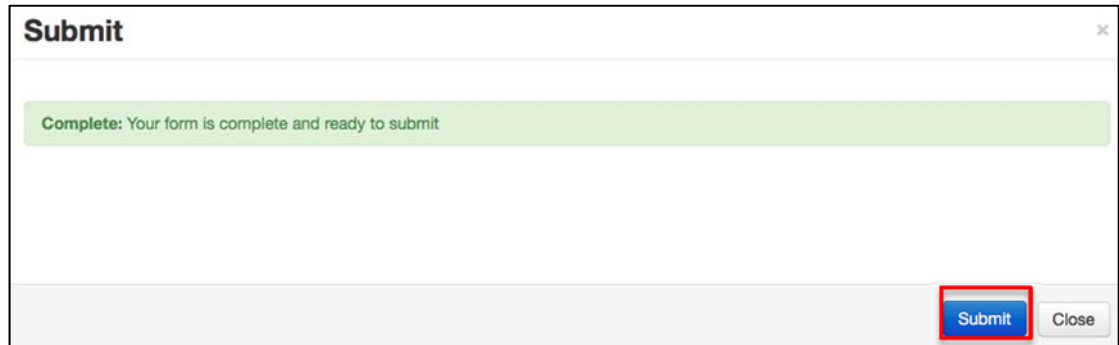
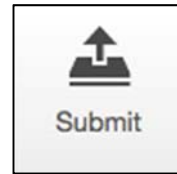
### **Additional Signatures**

If the form is locked (due to signature requests being sent), then additional signatories cannot be added to the form. In this situation, single-page forms for signing are available from the RCH Research Ethics and Governance webpage.

Alternatively, additional signatories can be added when queries are issued.

## Submitting forms

1. Select a form from the project tree.
2. From the actions menu, click on the submit button.
3. The system will run a check for completeness. This will bring up a list of outstanding or incomplete questions that you can navigate to.
4. If all the outstanding items are completed, use the “submit” button to submit the form.



5. On successful submission you will be re-directed to a page congratulating you on your submission.

## Submission History

1. To view submission history, click the Submissions tab.
2. This will display a page with the submission history on a table, detailing the date it was submitted along with the opportunity to download the submitted form.

## Printing a form

1. Click the Print tile located on the side navigation bar.
2. A PDF of the form will be generated that you can download or print.

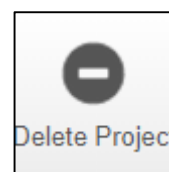


## Deleting a Form or Project

Up until a form is submitted, it can be deleted. A project can be submitted up until any form within it is submitted.

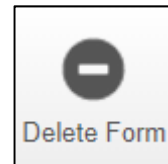
### Deleting a Project

1. From the Work Area, or the folder in which the project is stored, Click on "Delete Project".
2. Select the project that you wish to delete from the drop-down menu.
3. Click on "Delete".



### Deleting a Form

1. Select the form that you wish to delete.
2. From the Actions menu, click on "Delete Form".
3. Click on "Delete".

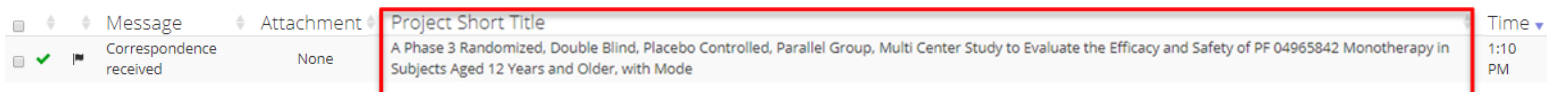




## Queries and Correspondence

The REG office staff will send correspondence requesting information about a project through ERM. The message will include instructions on how to re-submit the project.

1. In your notifications inbox, click on the project title. This will take you to the project.

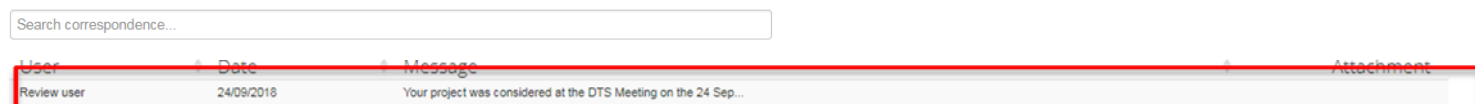


2. Click on the Correspondence tab.



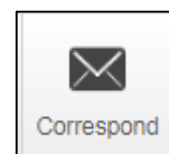
3. Click on the correspondence to see the message.

### Correspondence



### Responding to DTS Queries

1. You will get an email notification sent through ERM to let you know that information has been requested. Attached to this email will be a queries letter instructing researchers to respond and make required changes via ERM.
2. If you have been asked to update documents, this needs to be done within the form. Remove the existing documents from the form and upload the updated ones in their place. Make sure they are labelled with the correct version number and date. For more information, see the [Attaching Documents](#) section.
3. If you have been asked to update a form, navigate to the relevant question and update the information.
4. Provide a response to queries addressing each point in the letter, and upload the letter in the documents section.
5. Use the Correspond button for other minor queries or clarifications with the ethics office.



## HREC queries

### Viewing HREC queries

For HREC queries, you will receive a notification generated through ERM, including the queries letter.

### Responding to HREC Queries

1. If you have been asked to update documents, this needs to be done within the form. Remove the existing documents from the form and upload the updated ones in their place. Make sure they are labelled with the correct version number and date. For more information, see the [Attaching Documents](#) section.
2. If you have been asked to update a form, navigate to the relevant question and update the information.
3. Provide a response to queries addressing each point in the letter, and upload the letter in the documents section.
4. Use the Correspond button for other minor queries or clarifications with the ethics office.

Where the system requires an additional signature after updates to the form, upload a PDF of the original form as [Other Evidence](#).

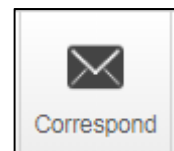
## Amendment Queries

### Viewing Amendment queries

Amendment queries will be sent either in the body text of the correspondence message, or as an attachment.

### Responding to Amendment Queries

1. If you have been asked to update documents, this needs to be done within the form. Remove the existing documents from the form and upload the updated ones in their place. Make sure they are labelled with the correct version number and date. For more information, see the [Attaching Documents](#) section.
2. If you have been asked to update a form, navigate to the relevant question and update the information.
3. When you are ready to reply to the queries, click on the Correspond button.
4. Provide a response to queries addressing each point in the letter, and upload the letter in the documents section.
5. Use the Correspond button for other minor queries or clarifications with the ethics office.



## General Correspondence

For matters that the HREC needs to be made aware of but are not a submission, or if you have questions for the HREC, the Correspondence function can be used. To correspond with the HREC:

1. Click on the Correspond button in the Actions menu.
2. You can type a message and attach any relevant documents.
3. Click “Send” to send the correspondence.
4. When you send, the receiver will see a Notification in their Notifications tile.

## Amendments

### Amendments for Lead Sites and Single Site studies

The lead site creates the amendment form under the HREA. This can serve as notification to the lead-site RGO as well, depending on site requirements. The RGO at RCH accepts this form as notification of the amendment.

1. Create the Amendment Request.
2. Complete the form. Make sure to detail the changes that are being made and the reasons for these changes. The reasons for the changes should explain the justification for the changes.
3. Upload all documents that are part of the amendment.
4. Request signature
5. Do not submit until you have either the electronic signature from the PI or some other evidence that you can upload in the documents section (e.g. a copy of an email from the PI endorsing the amendment, a copy of the signed RCH amendment form). If this is not provided it will be sought as part of the REG review.
6. Submit the form.
7. Check for queries as per [Amendment Queries](#).
8. Approval letters will be issued by email.

### Amendments for accepting sites (Governance only submission)

Accepting sites use a “site notification form”, created under their SSA, and attach the approval of the amendment to submit to their RGO.

1. Navigate to the SSA form.
2. Create the Site Notification Form using [Create Sub-forms](#).
3. Complete the form, including investigator information, a summary of the amendment.
4. Attach all relevant document, including the HREC approval letter. Make sure the details of the amendment are clear in the documentation. If it is not clear the RGO will request this information

You may upload the lead site amendment form to assist with review.

5. Do not submit until you have either the electronic signature from the PI or some other evidence that you can upload in the documents section (e.g. a copy of an

email from the PI endorsing the amendment). If this is not provided it will be sought as part of the REG review.

6. Submit the form.
7. Check for queries as per [Amendment Queries](#).
8. Approval letters will be issued by email.

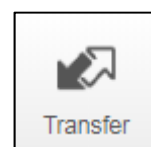
## Project transfers

To view transfer history simply click the History tab. This tab will display all the transfer history, detailing the user to user, dates and status along with the opportunity to cancel the transfer before it takes place.

### Transferring a project to a new owner

You can only transfer a project if you are the project owner. When you transfer the Project, you lose access to that project – unless the new owner shares the forms with you.

1. From the work area, select Transfer from the actions menu.
2. Enter the email address of the person you want to transfer the project to.
3. Enter a message to the person you are transferring the project to.
4. Select the project from the list by checking the box.
5. Click Transfer.



### Transfer Projects

Please note that you will lose all access to this project.

Email Address

Enter a message (optional)

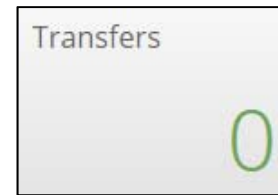
Search Projects

User Project Id	Project Title
<input type="checkbox"/> 42973	Demonstration Project (HREA)
<input type="checkbox"/> 43982	Demonstration project 2 (no sub-forms)
<input type="checkbox"/> 43996	Demonstration project 3 (ready to sign)
<input type="checkbox"/> 44001	Demonstration project 4 (ready to submit)
<input type="checkbox"/> 44298	Demonstration project 3 (ready to sign)
<input type="checkbox"/> 44320	Demo study 6
<input type="checkbox"/> 44479	Demo 7
<input type="checkbox"/> 46948	Demo 9
<input type="checkbox"/> 46957	demo MDF

**Transfer** Close

### Accepting a study transfer

1. Click on the Transfers tile.
2. A list of all transfers (in and out) will be displayed.
3. To accept a transfer, click on Accept Transfer.



## Collaborators

If you only want to share the application in question, click on the "Share" tile within the Action pane and enter the email address of the person you wish to share the form with. NOTE: they will not be able to view up the branch of the project.

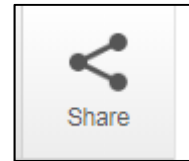
If you want them to view the application in question and applications up the branch, e.g. to be able to read the subform and make changes etc AND be able to view the main form, click on the "Roles" tile within the Action pane, select the level of access and enter the email address of the person you wish to share the forms with.

Once you have shared a form using "Roles" you can click on the Collaborators tab to check the permissions given and you can always modify the permissions to give them more or less access. The importance of using "Roles" is to give the recipient read access to the main form.

Share all your Projects with appropriate personnel as soon as possible following the start-up of ERM. When creating new forms in ERM, share them with appropriate personnel as soon as possible.

### Sharing a form

1. Click the Share tile located on the side navigation bar.
2. Enter the email address of the person you wish to share your form with.
3. Select the access this collaborator will have to the form:
  - Read Only Access: only allows the collaborator to read the form.
  - Read/Write: allows the collaborator to read and write on the form.
  - Full Access: allows the collaborator to read, write, share and submit the form. Gives the same permission over the form as the original owner has.

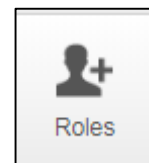


Sharing a form shares only that form, and not the sub forms.

### Roles

Permissions and access can also be given using applicant roles, which give the collaborator the corresponding set of permissions. The Roles action enables you to share multiple forms within a Project with a collaborator.

1. Click on Roles in the Actions Menu.
2. Enter the email address of the person you wish to share with. Enter permissions for multiple people by clicking the + button.
3. Select the appropriate pre-defined role.
4. If this person does not have an ERM account, an invitation will be sent to them to create one. Once they have created an account, you can share with them.





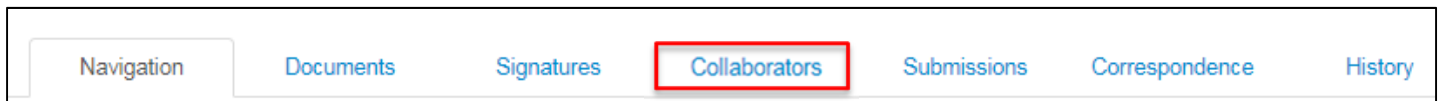
5. If you need to modify permissions given to a study team member, use the Collaborators tab to Edit Permissions.

**This will give the study personnel access to the HREA only.** If they also need to be able to view all existing sub-forms, then use the Roles action on the last sub-form submitted, following the above process.

### Viewing and Editing Collaborators

If permissions are not adequate or need to be altered, they can be edited.

To view form collaborators:



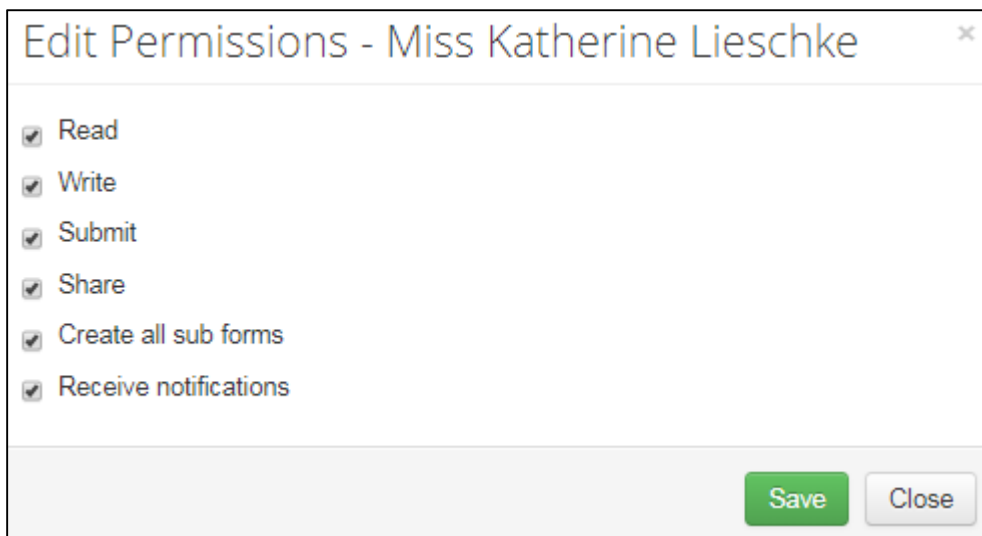
1. Click the Collaborators tab.
2. This tab will display all the form collaborators, detailing the collaborator name, their access and status of the collaboration along with the opportunity to revoke collaborator access.

To change permissions for a person:

1. From the Collaborators tab, click on Edit Permissions

Name	Access	Edit Permissions
Miss Katherine Lieschke	Read, Write, Submit, Share, Create all sub forms, Receive notifications	<input type="button" value="Edit Permissions"/>
[REDACTED]	Read, Write, Create all sub forms, Receive notifications	<input type="button" value="Edit Permissions"/>
Ms A Syneos Health	Project Owner and Form Owner	<input type="button" value="Edit Permissions"/>

2. Check the boxes to indicate which permissions you want to give the person.

A dialog box titled 'Edit Permissions - Miss Katherine Lieschke' with a close button (X) in the top right corner. It contains a list of permissions, each with a checked checkbox: Read, Write, Submit, Share, Create all sub forms, and Receive notifications. At the bottom right, there are two buttons: a green 'Save' button and a grey 'Close' button.

## Notes on Roles and sharing

- For a collaborator at another site, to share the HREA and allow the collaborator to create and submit sub forms, assign the role “Read, Create Sub forms” to the collaborator on the HREA. This will not allow the collaborator to edit or submit the HREA.
- Assigning a collaborator the role of SSA Share on the SSA form will allow them to see the SSA form and perform all actions on this form, but will not allow them to see any existing sub-forms under that SSA. They will be able to create new sub-forms.
- Under both the HREA and SSA, giving a post approval/authorisation Subforms access to a collaborator grants access only to that form.

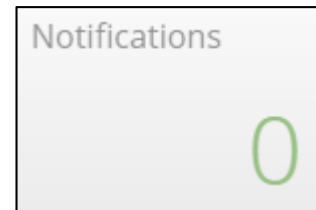
## Notifications, and other system messages

The Notifications tile shows the number of unread notifications in red. It is like your email Inbox.

Click on the Notifications tile to view your notifications.

You can mark Notifications as unread or read, flag them and delete them.

Always check Notifications when you login as you may receive notifications from the HREC or RGO Administrators.



## Updating a Form or Project

If the form or project requires an update, a banner will appear at the top of the browser.

**Note:** There is a newer version of the project. [Update](#)

Simply click the Update text and the form will be updated. This will invalidate all signatures on forms that have not been submitted.

If you do not own the form or project, you will need to contact the form owner to have it updated.

**Note:** There is a newer version of the project. *(Please contact the project owner to update this form).*

Some updates must be applied for forms within the project to be created or submitted.



## Summary of submission requirements

This table is designed as a guide to the requirements for submissions of new studies and post-approval processes in ERM.

Submission	Form(s)	Attachments	Signatures
New submission – LNR Single Site	HREA VSM	As per <a href="https://www.rch.org.au/ethics/new-applications/Low_and_negligible_risk_research/">https://www.rch.org.au/ethics/new-applications/Low_and_negligible_risk_research/</a>	PI AIs Head of Department/Line Manager
New submission – LNR Multi-Site	HREA VSM SSA	As per <a href="https://www.rch.org.au/ethics/new-applications/Low_and_negligible_risk_research/">https://www.rch.org.au/ethics/new-applications/Low_and_negligible_risk_research/</a>	PI (HREA and SSA) AIs (SSA only) Head of Department/Line Manager (SSA only)
New submission – Greater than Low Risk Single Site	HREA VSM	As per <a href="https://www.rch.org.au/ethics/new-applications/Single-site_research/">https://www.rch.org.au/ethics/new-applications/Single-site_research/</a>	PI AIs Head of Department/Line Manager
New submission – Greater than Low Risk Multi-Site	HREA VSM SSA	As per <a href="https://www.rch.org.au/ethics/new-applications/multi-site/">https://www.rch.org.au/ethics/new-applications/multi-site/</a>	PI (HREA and SSA) AIs (SSA only) Head of Department/Line Manager (SSA only)
New submission – Governance Only Lead HREC is in VIC or QLD	Site Specific Application Form	As per <a href="https://www.rch.org.au/ethics/new-applications/Governance_only_%E2%80%93_SSA/">https://www.rch.org.au/ethics/new-applications/Governance_only_%E2%80%93_SSA/</a>	PI AIs Head of Department/Line Manager
New submission – Governance Only Lead HREC not in VIC or QLD	Minimal Dataset Form	As per <a href="https://www.rch.org.au/ethics/new-applications/Governance_only_%E2%80%93_SSA/">https://www.rch.org.au/ethics/new-applications/Governance_only_%E2%80%93_SSA/</a>	PI AIs Head of Department/Line Manager
Amendment	Amendment Request	Any updated or new documents	Coordinating PI
Amendment – Governance Only		Any updated or new documents HREC approval letter	Site PI
Annual Report	Project Progress Report	Attachments not currently possible.	Coordinating PI
Annual Report – Governance Only	Site Progress Report	Attachments not currently possible.	Site PI

Annual Safety Report	Annual Safety Report	Attachments not currently possible.  For Commercially sponsored trial: DSUR (or equivalent), if provided. Please submit using <a href="#">Correspondence</a> function	Sponsor
Annual Safety Report – Governance Only	Site Notification Form	Any relevant supporting documentation	Sponsor
Serious Breach	Serious Breach Report	Any relevant supporting documentation.	Coordinating PI
Suspected Breach	Suspected Breach Report	Attachments not currently possible.	Coordinating PI
Change of Investigator	Amendment Request	Investigator CV	As per amendment submission
Site Closure	Site Closure Report	Attachments not currently possible.	Coordinating PI
Site Closure – Governance only	Site Notification Form	Any relevant supporting documentation.	Site PI
Final Report	Project Final Report	Attachments not currently possible.	Coordinating PI
Updated Insurance Certificate (Commercial trials only)	Project Notification Form	Insurance Certificate	None
Updated Insurance Certificate – Governance Only (Commercial trials only)	Site Notification Form	Any relevant supporting documentation.	None
DSMB Reports	Project Notification Form	DSMB Report	None
DSMB Reports – Governance Only	Site Notification Form	Any relevant supporting documentation.	None
Other submissions/notifications	Project Notification Form	As required.	None
Other submissions/notifications – Governance Only	Site Notification Form	Any relevant supporting documentation.	None

## FAQ

### Creating Subforms

I cannot see the option for creating a subform

There are two possible issues. If you are not the project owner, you may not have permissions that allow you to make subforms. Check the Permissions tab and contact the form owner to [adjust permissions](#) if necessary.

The other possibility is that there has been a system update to the form or project that needs to be applied before subforms can be created. If there is a banner across the top of the page indicating that there is an update for the project/form, you will need to click update or contact the project/form owner to [have the project/form updated](#).

### Completing forms

When I click on “Completion check” I get a message that a field is not complete but I have entered the information

This happens when the field has two lines for information and you have only used one. In the line that is blank, enter a single character (a space should be sufficient) and run your completion check again.

### Signatures

What signatures do I need for amendment and new applications?

**NEW APPLICATIONS:** The PI needs to sign the HREA and the AI’s and head of department sign the SSA.

If completing a new application there is the option to upload wet ink or “other evidence” if the electronic signature from the PI is not available. Other evidence could include a copy of an email from the PI endorsing the application.

**AMENDMENTS:** The PI will need to provide an electronic signature or some form documentation will need to be uploaded (e.g. a signed amendment form) to the amendment form. Refer to [Amendments](#) for information on submitting amendments.

I have outstanding signatures but the form has been submitted and locked

After submission, the form is locked for review. Electronic signatures are not possible while the form is locked.

If you have outstanding signatures at submission, you can use one of the local REG template available at [https://www.rch.org.au/ethics/researcher-resources/Forms\\_and\\_templates/](https://www.rch.org.au/ethics/researcher-resources/Forms_and_templates/) and upload to the documents section when you respond to queries.

This is most relevant to SSA forms, where Head of Department and Supporting Department signatures are often not available at submission.



## Reference numbers

What reference number do I use?

The local reference number should be used to talk to the REG office and supporting departments.

The 5 digit project ID number should only be used when talking to Infonetica.

Must I enter the local reference number when completing the HREA?

Yes you must; this is the number the ethics office will use to communicate with you. If you do not have one then please complete a [Presubmission Form](#).

## Transferring applications

How do I transfer an application?

Please see [Transferring a project to a new owner](#).

ERM is not letting me create a subdocument.

Check the permissions on your form. You may need to ask the owner of the form to update your permissions. See [Collaborators](#) for information about sharing forms and permissions.

## VSM

Do I have to submit a VSM?

The Victorian Specific Module is built into the HREA, you will be asked to complete a VSM whenever you complete a HREA. For many studies, such as LNR projects, a VSM is not required. Please first complete the front sheet of the VSM. If all 3 questions are answered "No" then the form does not need to be completed and upload the first page only.

## SSA

Do I have to submit an SSA?

An SSA is only required for multisite studies. In this case the HREA should contain high level study information, and the details of the CPI and site PIs only. The SSA submitted at RCH should contain the site specific information and the details of the study team here.

For single sites studies the HREA should contain all the relevant site information and details of all study team members.

If you later amend a single site study to be multisite you may be required to submit an SSA.

## Notification email from ERM

Will I receive an email every time something is actioned in ERM by the ethics office?

Not all actions by the ethics office in ERM will generate an email notification. Applicants must check ERM for all updates. Where possible the ethics office will endeavour to send emails to remind researchers to check ERM for updates.

## Governance only applications

Can I create an SSA for non-Victorian sites in ERM?

Only Victoria and QLD sites are using ERM. For governance only applications from other national sites (NSW, WA, SA, TAS, ACT) that require an SSA, applicants will need to complete a minimum dataset form for the approving site (e.g. if Westmead is the approving site a minimum dataset form will need to be completed) then an SSA can be linked to the form. Please see the [Victorian Government website](#) for more information.

How do I get the information from the HREA to the SSA form?

Unfortunately due to licensing restrictions imposed by the owner of the HREA, the NHMRC, the information does not populate from the HREA to the SSA form. Researchers will need to cut and paste the information.

Please note that an SSA is only required for multisite studies.

## Duplicating a form

Can I duplicate a HREA?

A HREA can be duplicated, however this is **not recommended**. Duplicating a project copies all of the forms and none of the attached documents. It would only be useful if you were doing a new project that was very similar.

## Uploading documents

Will all my documents from the study be available through ERM?

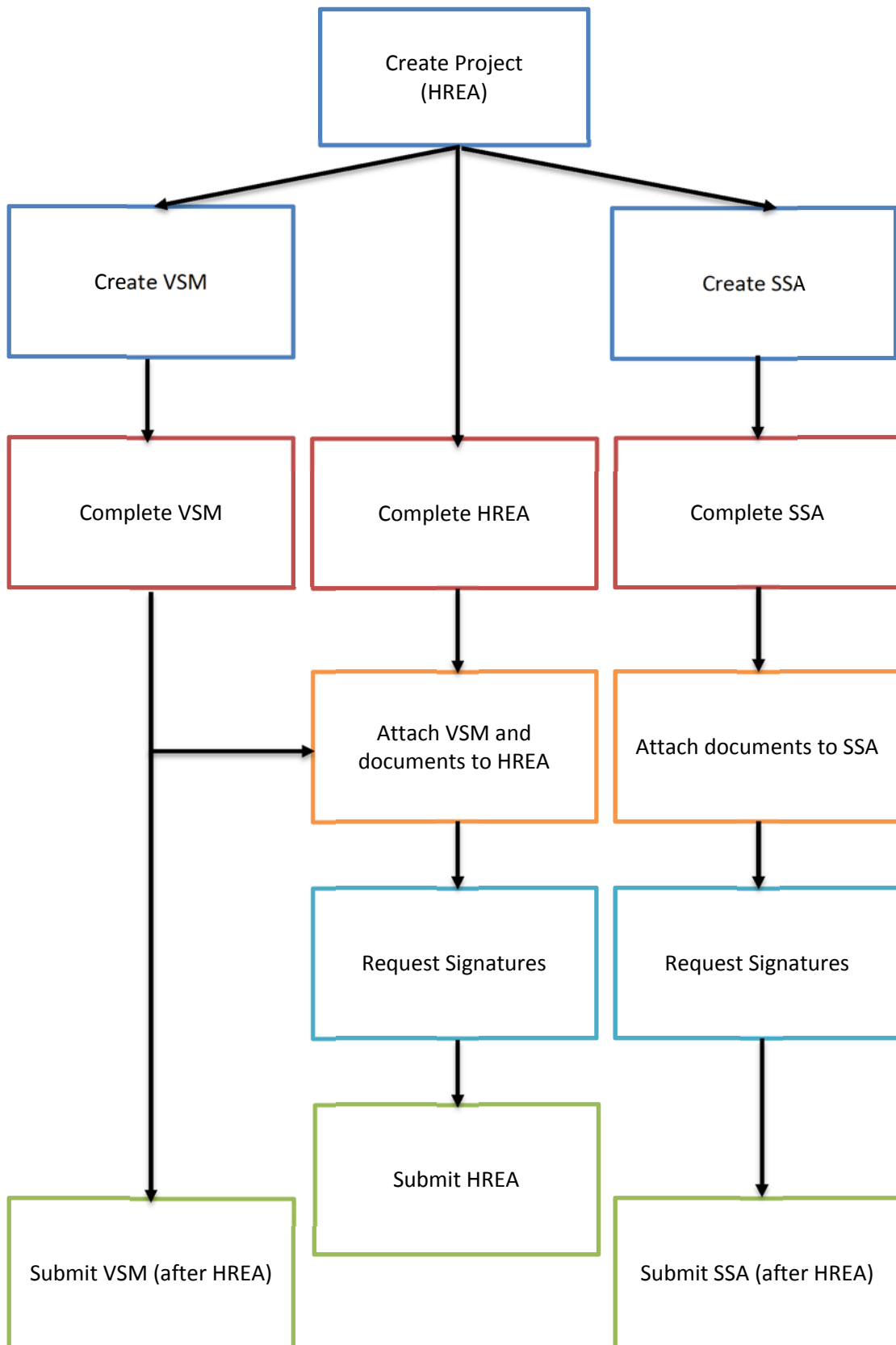
A full suite of documents will not be available to the researchers on ERM. Only projects that have been submitted through ERM or merged from the AURED will have documents available and these will only be those that were uploaded by the research team at the time of the initial application. Approval letters are not currently available through ERM.

Can I use ERM as a document repository for my project?

The Ethics Office is not using ERM as a document repository at this time but may do so in the future. Researchers could choose to use it for new projects going through ERM however please note that there is no set process for this yet.

# PROCESS FLOW CHARTS

## Submission of new study



## Submission of new study (Governance Only)

