Ethics Review Manager (ERM)

User Guide for Researchers

mater research

Contents

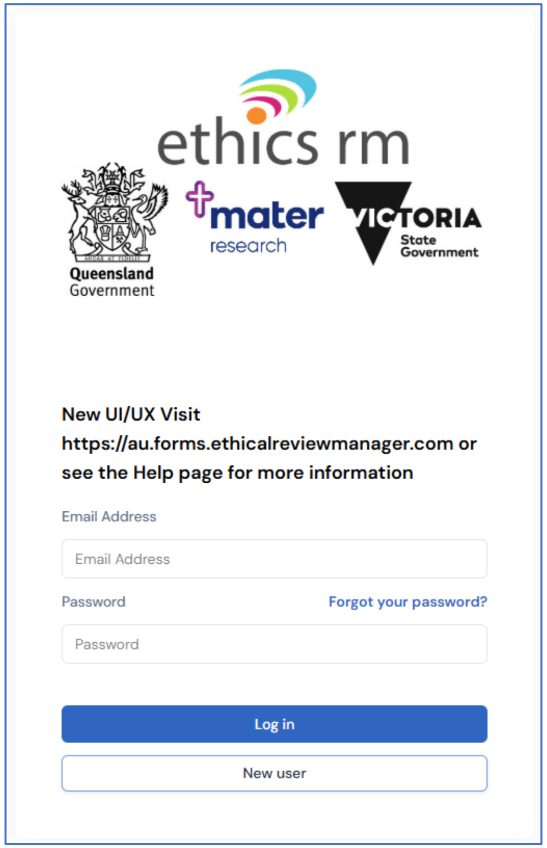
Introduction

Welcome to ERM!

ERM (Ethics Review Manager) is the platform for submitting all applications and reports to the Mater Human Research Ethics Committee and the Mater Research Ethics and Governance Offices.

Queensland Health and Department of Health Victoria also use ERM for this purpose, and Mater is sharing the ERM resources and data on multi-site projects with them. This means that if your study is conducted across sites in the Queensland Health and Department of Health Victoria jurisdictions, all details of your study will be contained in just one project within ERM.

All project forms and documents that you submit to these offices are stored within ERM, so they are easily referenced and organised.



Create a new account in ERM

- Go to au.forms.ethicalreviewmanager.com
- Click on **New User** and follow the prompts.
- If you are a Mater staff member, please use your Mater email address as your login address.
- When you click **Register**, ERM will send you a confirmation email, from which you may activate your new ERM account.

Login to ERM

- Go to au.forms.ethicalreviewmanager.com
- Enter your ERM login name (usually your regular email address) and password. If you can't remember your password, click **Forgotten Password** to reset your password.
- If you have trouble logging in, email the Infonetica Help Desk.

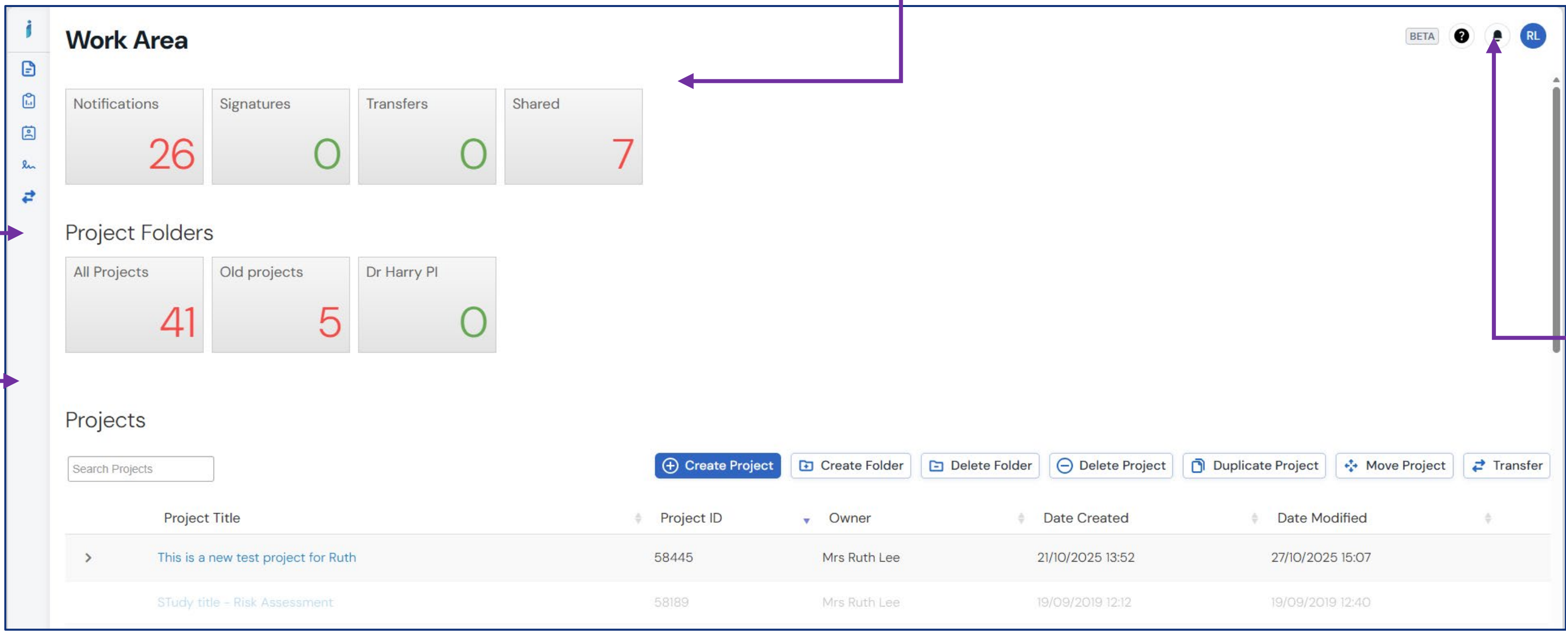
Work Area

This is your control dashboard.

The expandable menu on the left is always visible on all screens, allowing you to navigate back to the Work Area and other functions.

Tiles in the Work Area will open when you click on them to show the relevant listings. The numbers appear in red when they contain items that require action or have not been viewed by you.

Project Folders help you organise your list of projects.



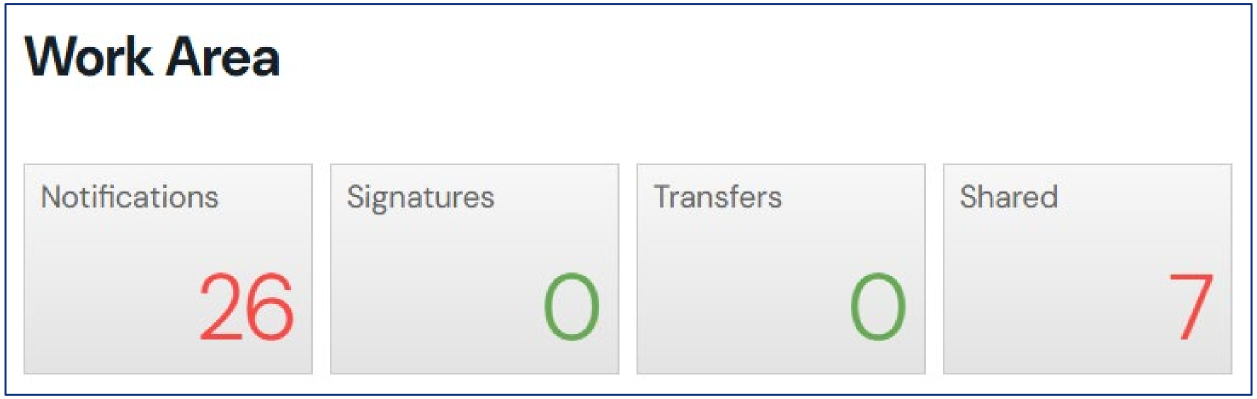
The **Help menu** contains a list of FAQs and responses, templates and contact information. It is recommended that you read the FAQs before beginning work in ERM.

Notifications are messages sent within ERM, like an internal email Inbox.

Action buttons allow you to perform a range of actions.

Projects are displayed in the Projects list. Only projects that you can access are listed here. Click on the > on the left of the project title to expand the project and view the forms within it.

Tiles in the Work Area



The **Notifications** tile contains messages sent from ERM. Further information is provided in the Notifications section.

The **Signatures** tile contains requests for your electronic signature. Further information is provided in the Electronic signatures section.

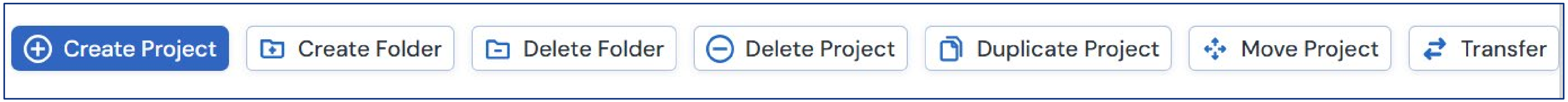
The **Transfers** tile contains a list of projects that have been transferred to you and transferred by you.

The **Shared** tile contains a list of forms that have been shared with you.

Actions in the Work Area

Actions allow you to perform these activities in the Work Area:

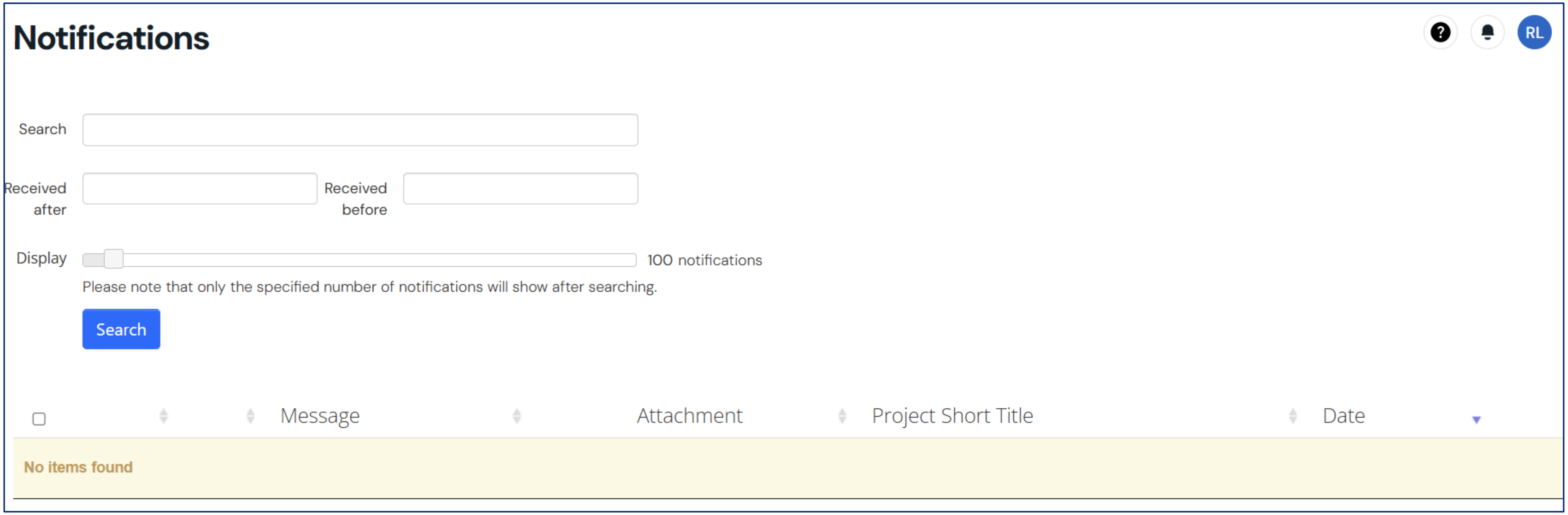
- Create Project – create a new project
- Create Folder – create folders to organise your projects
- Delete Folder – delete folders that you have created.
- Delete Project – delete a project (only possible if it contains no submitted forms)
- Duplicate Project – create a new project with the same forms as an existing project
- Move Project – move a project between folders
- Transfer – transfer ownership of projects to another ERM user



Notifications

Notifications are accessed from the tile as displayed above and from here in the Work Area. They are internal ERM messages.

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



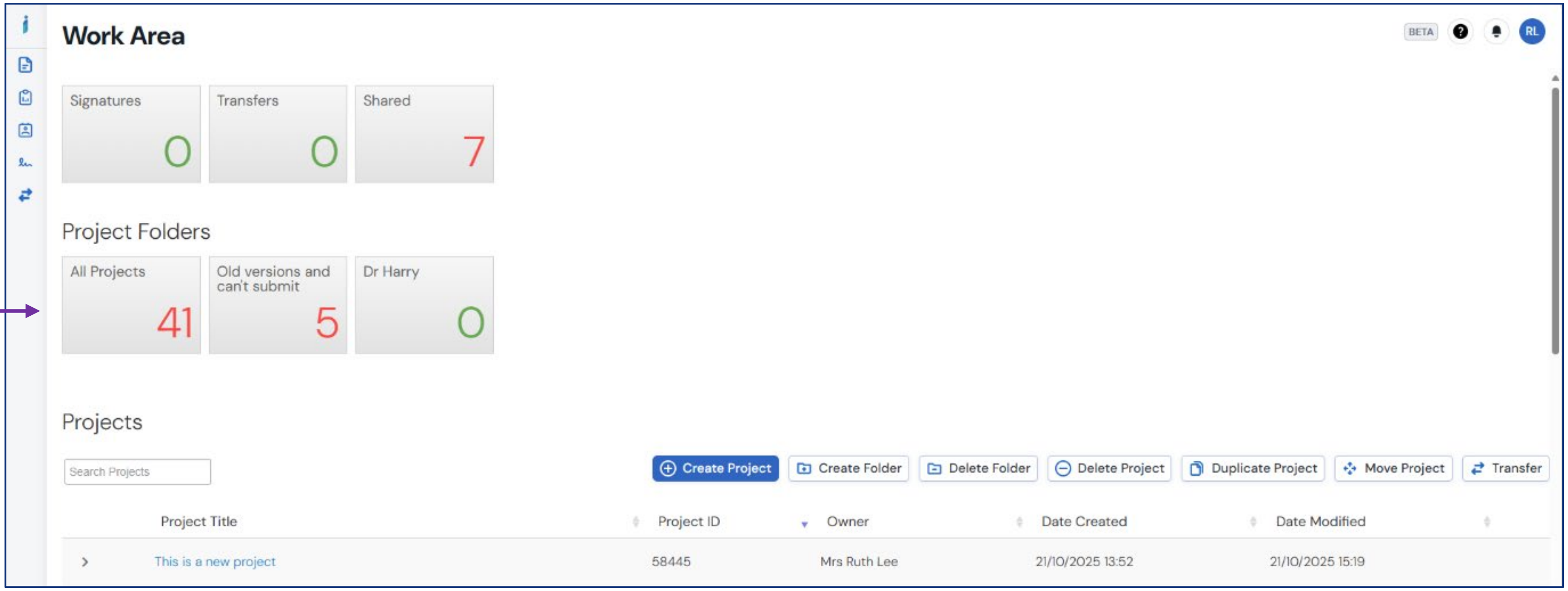
Hot tip! Always check Notifications when you login as you may receive notifications from the HREC or RGO Administrators. Note that you will also receive an email when a response is required from you regarding your submissions.

Folders in the Work Area

You can create folders to customise and organise your Work Area using the following actions:

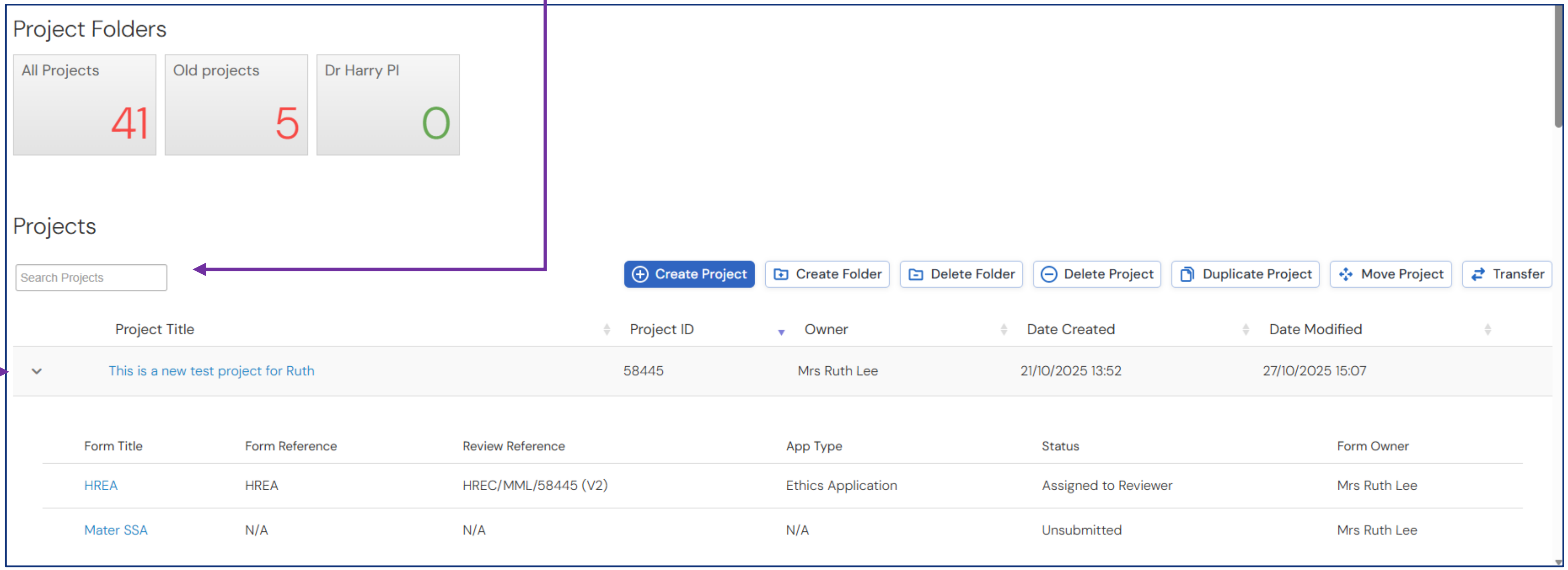
- **Create Folder**
- **Rename Folder**
- **Delete Folder**
- **Move Project** - Drag and drop projects from the Projects list into your folders

The **All Projects** folder contains all your projects. It is automatically created after you create the first folder.



Search for a project

To search for existing projects, use the **Search Projects** field above the list of projects in the Work Area or within the All Projects folder.



Your project may be in ERM, but you may not be able to see it if you did not create it or if the Project Owner has not given you access.

Consult with your study team members to see if they have access to the project in ERM. If so, they may be able to give you access.

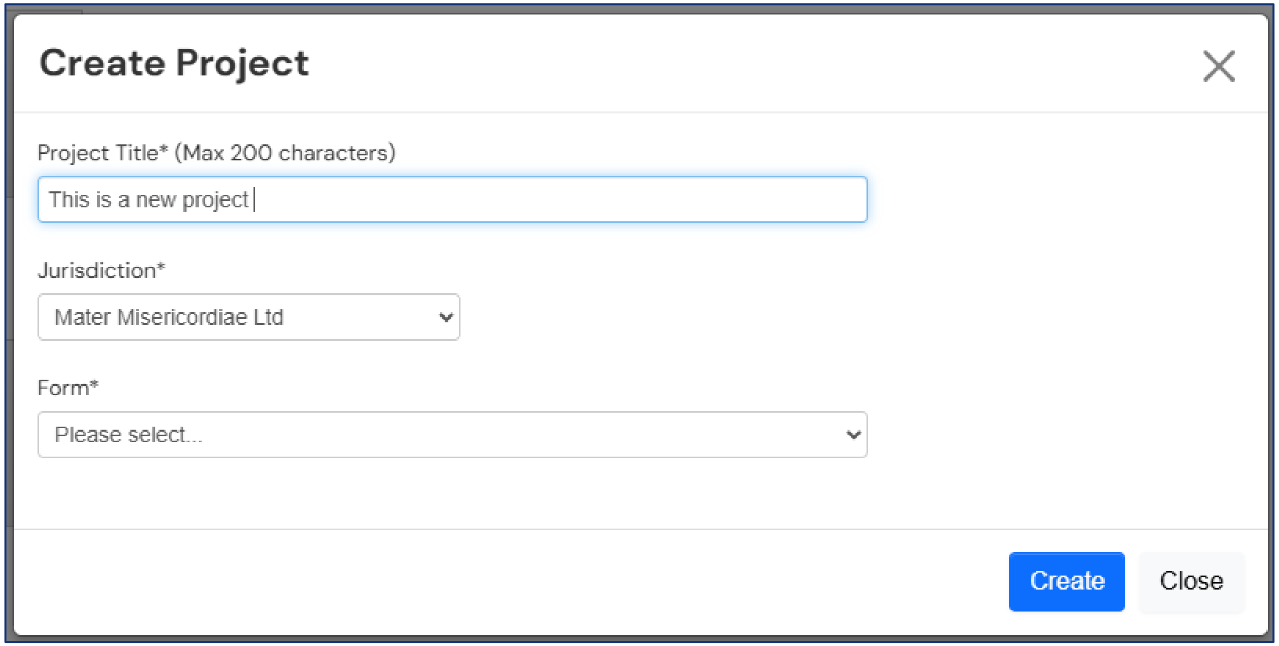
If no-one in your study team has access to the project, then contact either the [Mater HREC office](#) (if your project was approved by them) or the [Mater Research Governance Office](#), providing your Project Title and HREC review reference. They can search for your project. If it is in ERM, they can tell you who can give you access to the project.

Hot tip! Click the arrow beside the Project Title to display forms within the project.

Create a new project

In ERM, **projects** are comprised of one main form and nil, one or more subforms.

To create a new project, click **Create Project** action in the Work Area.



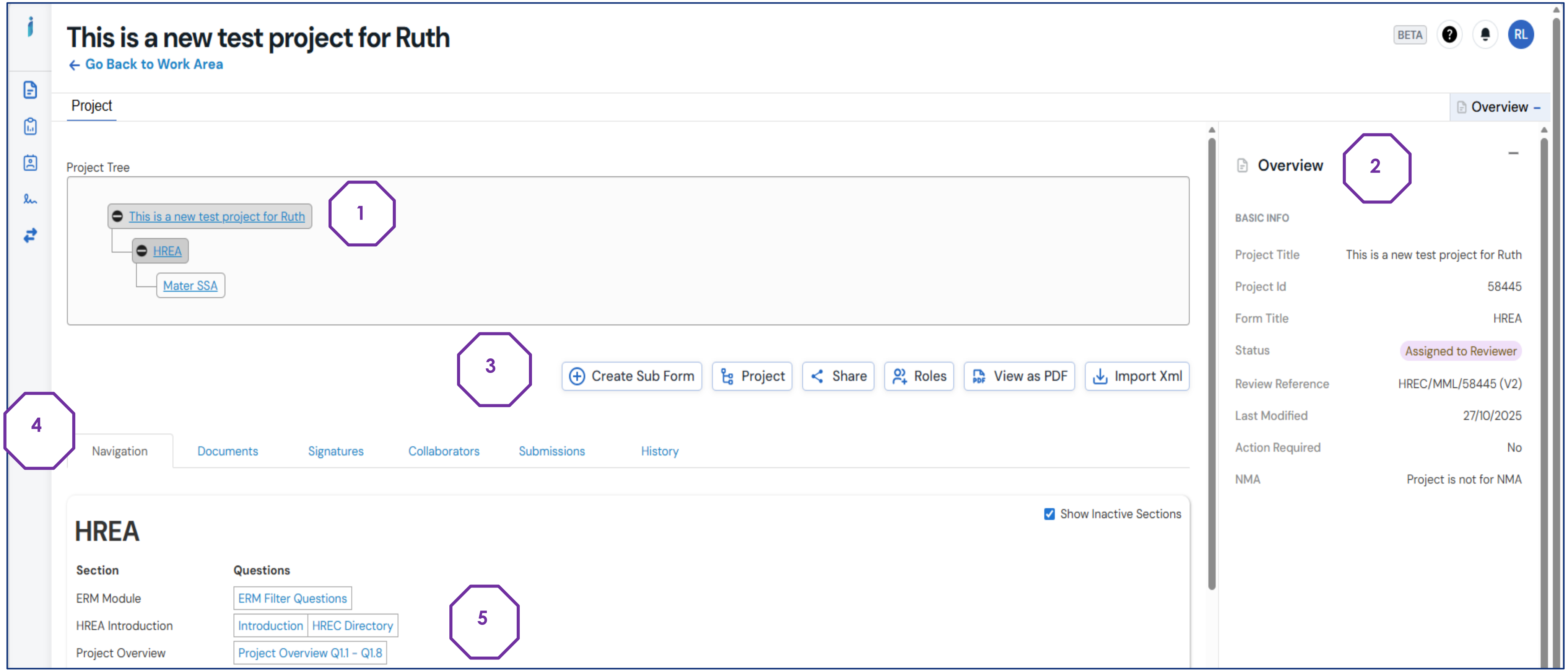
This will prompt you to enter a **Project Title**. It can be the full title or a short title of your project. It is restricted to 200 characters and can be changed within the main form. Ensure it is correct before application approval as it cannot be changed in ERM after approval.

Select the **Jurisdiction** containing the HREC that your study will be submitted to. If submitting to the Mater HREC, then select Mater Misericordiae Ltd.

Select a **Main Form** from the **Form** list. (Refer to Appendix A for guidance on main forms that can be submitted to Mater.)

Click **Create** to create your Project. A **Project ID** will be allocated. The **main form** will also be created and available for you to complete.

Click on the project in the **Projects** list to enter the project, view the main form and view available actions.



1 The **Project Tree** displays all forms in this project that you can access.

2 The **Overview** section contains information about the project and the highlighted form. It can be minimised by clicking the "-".

- **Project Title**
- **Project ID** – the unique project identifier
- **Form Title –** the title of the form that is highlighted in the project tree
- **Status** - displays the current status of the highlighted form.
- **Review Reference** - allocated when the form is submitted.
- **Last Modified** – the date the form was last modified
- **Action Required** - indicates if any action is pending on the form. Click 'Yes' to run the Completeness Check to list mandatory questions that have not been completed. This will display 'No' after all mandatory questions have been completed and the form has been submitted.
- **NMA** indicates if the project is conducted across multiple sites and needs to be shared with other sites in ERM ('Project is for NMA') or if it is only to be conducted at a single site ('Project is not for NMA').

3 A range of **Actions** are available on this screen. They are described in detail in the next section.

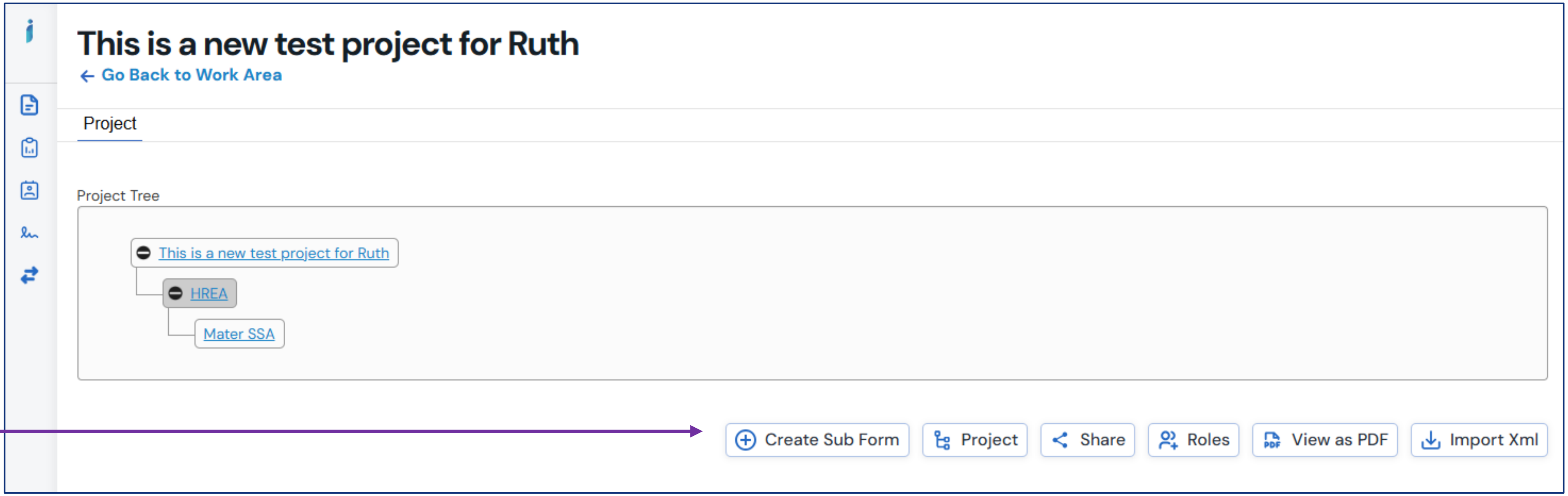
4 The **row of tabs** shows information that will be compiled as the form moves through the submission and review phases:

- **Navigation** – allows you to navigate directly to a section within the form
- **Documents** – displays documents uploaded within the form
- **Signatures** – displays electronic signatures entered on the form and signature requests that have been sent
- **Collaborators** – displays the Project Owner, Form Owner, and people who have been given access to the form.
- **Submissions** – displays all submissions of this form
- **History** – displays a record of all past events occurring on the form.

Hot Tip! Important items like Approval and Authorisation letters can be downloaded from the History. Find the relevant event within the history (e.g. "The Mater RGO has authorised your study") and click the **Download** button.

5 The lower section of this screen displays sections of the form. The sections in blue contain questions for completion. Click on the blue questions to navigate directly to that section, instead of paging through the form.

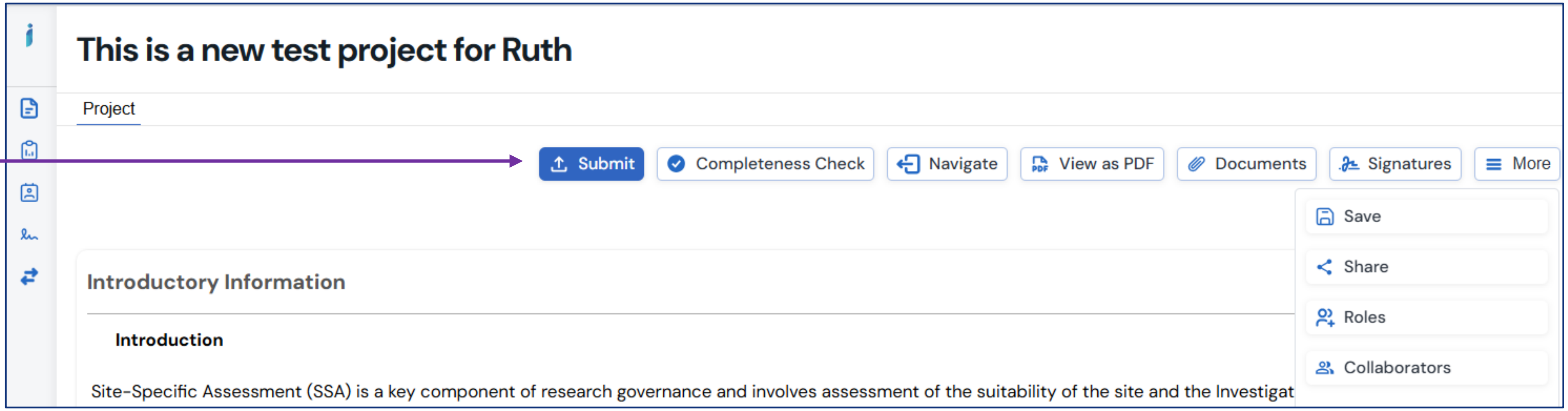
Actions within a project



Action Name	What does it do?
Create Subform	Creates a subform of the current form (refer to Appendix B for a list of Mater subforms).
Project	Takes you to the highest level in the project, displays the Project Tree, all project level information, and all forms including forms that you may not have access to.
Share	Allows you to share the current form with other users and set their permissions.
Roles	Allows you to apply a role to other study team members, giving them access to multiple forms in the Project. This is the preferred method of providing access. The access permissions are pre-defined. Refer to the Access to projects and forms section in this guide for more details.

Actions within a form

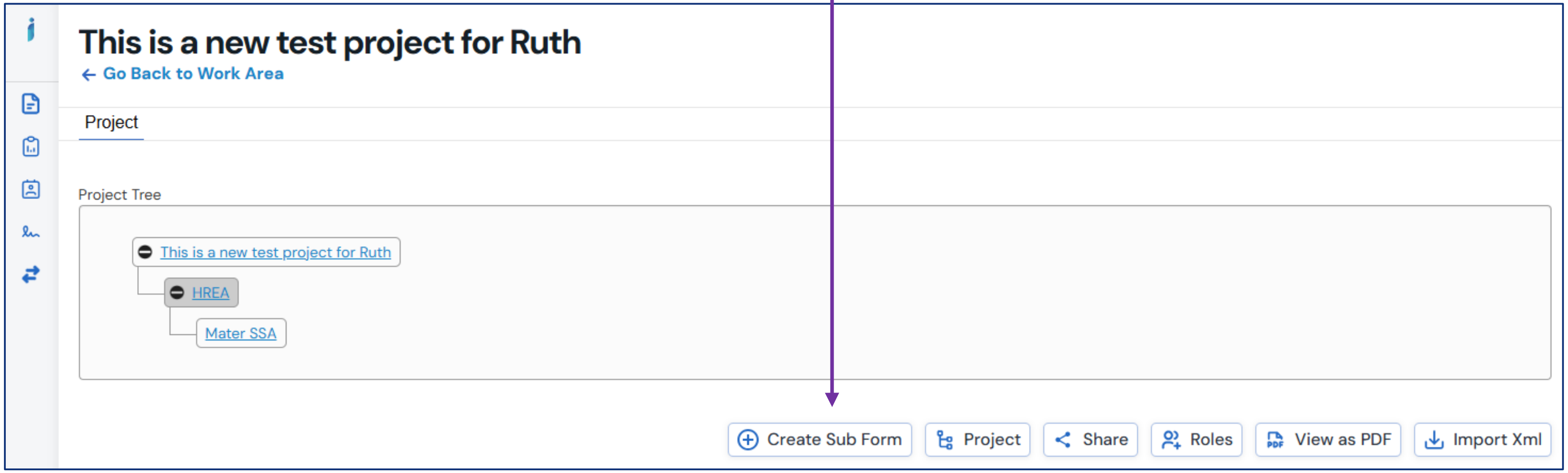
Highlight the form in the project tree then click on a blue question in the bottom section of the screen to access the form. These are the **Actions** you can now perform:



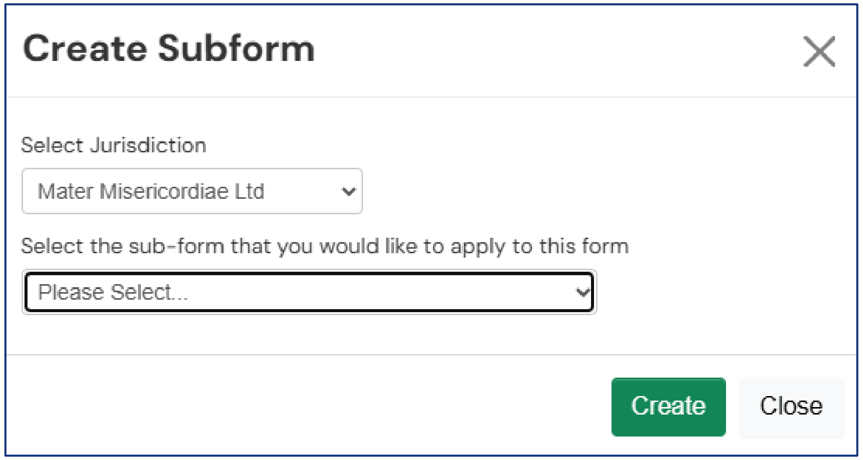
Action Name	What does it do?
Submit	Performs the Completeness Check; submits the form if all mandatory questions have been answered.
Completeness Check	Checks that all mandatory questions have been answered before allowing signatures and submission.
Navigate	Returns to the Project Tree screen. All changes will be saved.
View as PDF	Generates a pdf of the form in a new browser tab, for viewing, printing and saving.
Documents	Lists all documents uploaded into the form.
Signatures	Lists electronic signatures collected and the status of signature requests.
Within the More button	
Save	Saves the latest changes to the form. Navigating between pages performs auto-save.
Unlock (only displayed when form is locked)	Unlocks the form if changes are required after the form has been locked (by requesting or applying signatures).
Share	Shares the current form with other users and set their permissions.
Roles	Applies a role to other study team members, giving them access to multiple forms in the Project.
Collaborators	Displays the Project Owner, Form Owner, and people who have been given access to the form.
At bottom of each page	
Previous and Next	To navigate through the pages in the form. Changes will be saved as you move to a different page.

Create a subform

To create a Mater subform, click the main form in the Project Tree then click the **Create Subform** action.



Select the jurisdiction and the subform, then click **Create.**

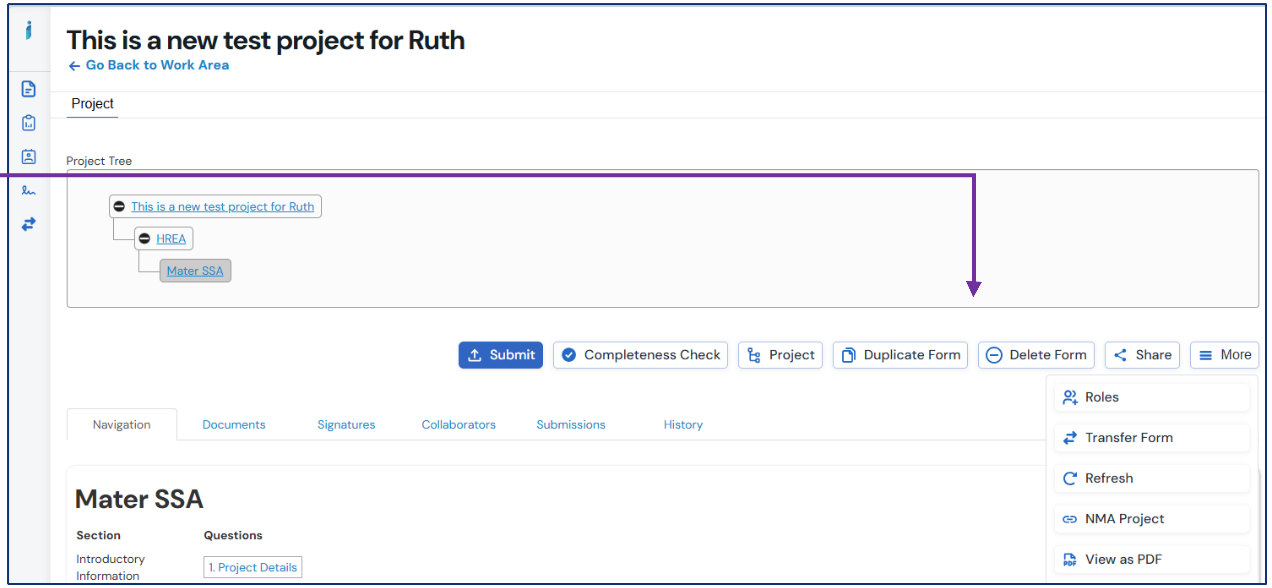


The subform will appear in the Project Tree.

When you have clicked on a subform in the Project Tree, additional subform-specific actions are available, including:

- **Duplicate Form** – Allows you to create a copy of the form
- **Delete Form** - A form can be deleted up until it has been submitted.
- **Transfer Form** – Transfer ownership

Complete the questions on the form by navigating through the pages, then submit in the same manner as the main form.



Withdraw a submitted form

You can withdraw a form after it has been submitted – but only before the reviewing office changes the status. After this point (when the reviewing office has commenced their review), you cannot withdraw the form, but the reviewing office can withdraw it for you.

To withdraw a submitted form, click the form in the Project Tree then click the **Withdraw Application** action.

Delete a form and/or project

You can delete subforms - if they are unlocked and not submitted.

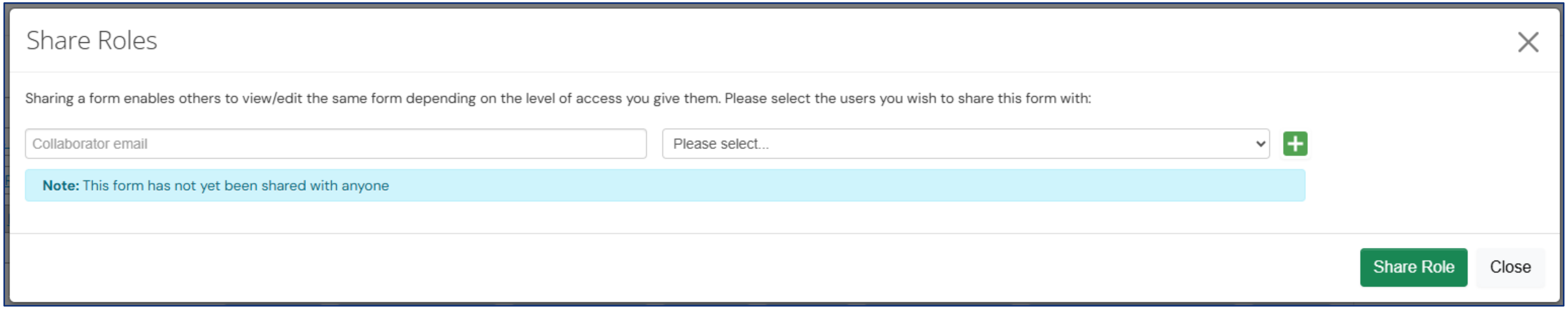
You can delete a project – if it contains no submitted forms. This is handy if you have created a project by mistake and realise this before you submit any forms within the project, or you have created a 'dummy' project for learning purposes that can be removed.
Subforms must be deleted first then the project can be deleted. Deleting the project also deletes the main form.

Access to projects and forms – Roles and Share actions

In ERM, access can be given to collaborators and other study personnel for the purposes of reviewing, signing, updating, creating and submitting forms. Their level of access is defined by you.
Access to projects can be given by using either the Roles action (the preferred action) or the Share action.
Access is provided at the form level, to either a single form or multiple forms.

Roles action

The **Roles** action can provide access to the main form **or** all subforms and the main form within a project, **in one step**, according to a set of pre-defined permissions (roles). It is a fast method of sharing forms, but care needs to be taken to ensure appropriate permissions are allocated.



To provide access to the **Main form only**:

- Click on the project
- In the Project Tree, click the **Main form** (e.g., HREA, MDF, or DM HREC MDF.)
- Click the **Roles** action
- Enter the ERM email address of the person you wish to share with. Enter permissions for multiple people by clicking the + button.
- Select the appropriate **Main forms** role from the dropdown list (refer to Appendix C for a detailed list of the predefined Mater permissions)
- 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 give them a Role.
- If you need to modify permissions given via a Role, use the **Roles** action to remove and re-apply a role.

To provide access to all Mater subforms in the project:

- Click on the project
- Click on **any Mater subform** in the Project Tree
- Click the **Roles** action
- Proceed as per the instructions for the Main form, selecting the appropriate **Subforms** role from the dropdown list.
- **Note:** These roles will provide either Read access or Read and Create Subform access to the Main form as well.

To provide access to the Main form (submitted to Mater) and all Mater subforms in the project:

- Click on the project
- Click on the **Main form** in the Project Tree
- Click the **Roles** action
- Proceed as per the instructions for the Main Form, selecting the appropriate **Full Project** role from the dropdown list.
- **Note:** Full Project access is recommended for PI's and team members who need to create and submit forms. Use care when applying these roles.

To provide access to the Main form and the Mater SSA only in the project:

- Click on the Project
- Click on the **Mater SSA** in the Project Tree
- Click the **Roles** action
- Proceed as per the instructions for the Main form, selecting the **SSA Signatory** role from the dropdown list.
- **Note**: **SSA Signatory** access is recommended for signatories who may need to read documents attached to the main form and the SSA.

Important! When the main form has been submitted to another jurisdiction (i.e. either Queensland Health or Department of Health Victoria), these Mater-defined roles cannot provide access to the main form. So, in addition to applying a role whilst clicked on a Mater subform, you will also need to click on the main form and use the Roles action to find a suitable role that will provide Read and Create Subform access to the main form. If an appropriate role is not available, use the Share action instead.

Removing a Role

To change permissions applied by a role, the role must be removed, and a new role applied.

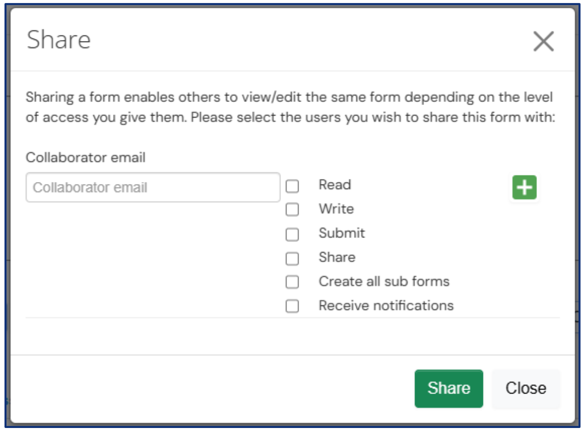
To remove a role:

- Click on the project
- Click on the relevant **form**
- Click the **Roles** action
- Click **Remove** for the user/s for which the role is being removed

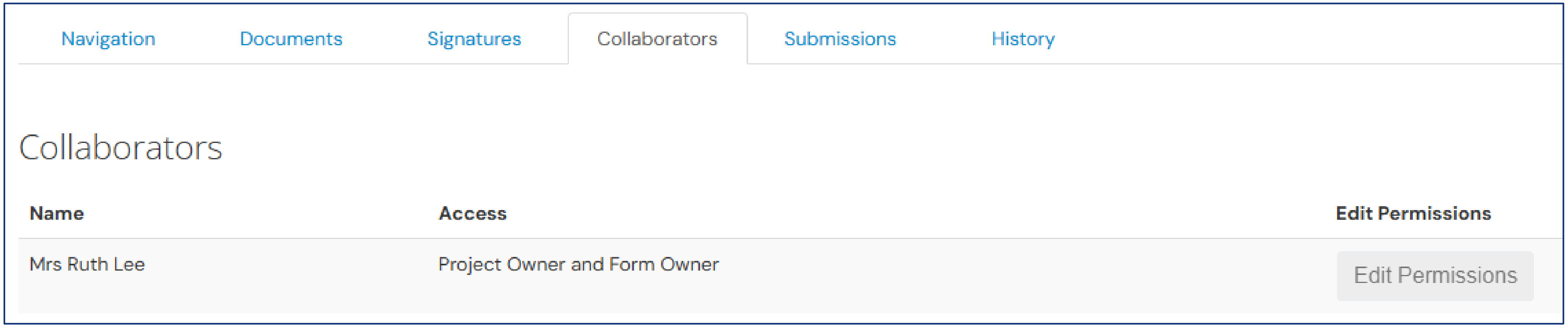
Share action

If study team members need to access a specific form only (either a Main or a subform), then use the **Share** action instead of the Roles action. This will give permissions for the **selected form only.**

You specify the appropriate permissions as required.



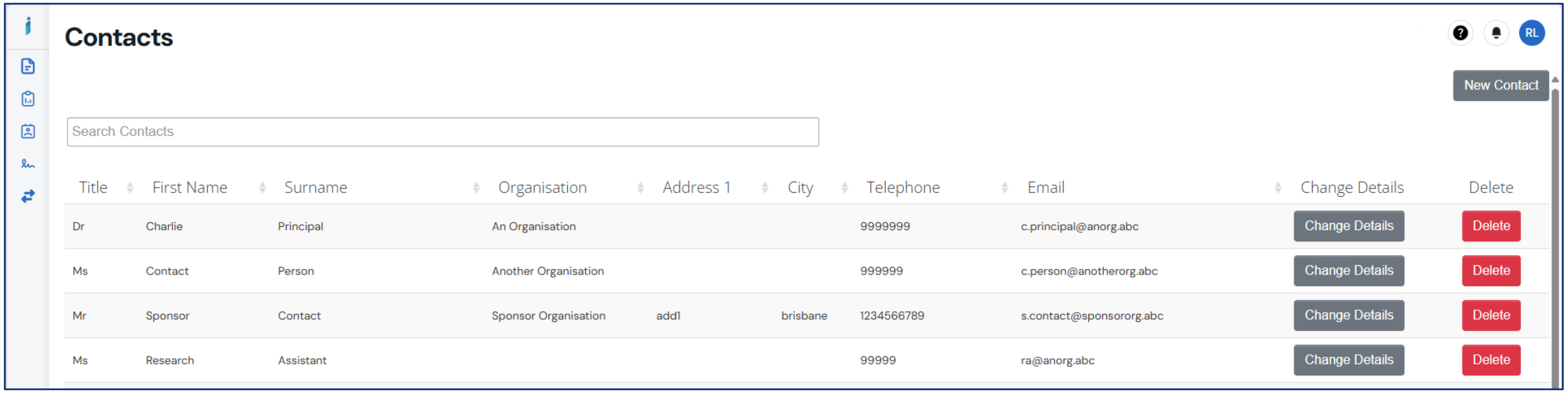
If you need to modify permissions given to a study team member via the Share action, use the **Collaborators** tab to Edit Permissions.



Contacts

You can keep your personal list of contacts in ERM.

Click the **Contacts** menu item in the side bar to add and update your contacts.



In addition to the above method, a more convenient method of adding contacts to your list is via the Contact questions within forms.

After entering contact details for the first time in a Contact question in a form, click the **Add to Contacts** button. This will save the contact details to your Contact list.
The next time you need to enter these details, click **Load** to select their details from your Contact list instead of re-entering them.

Electronic signatures

Signatures on all Mater ERM forms are collected electronically.

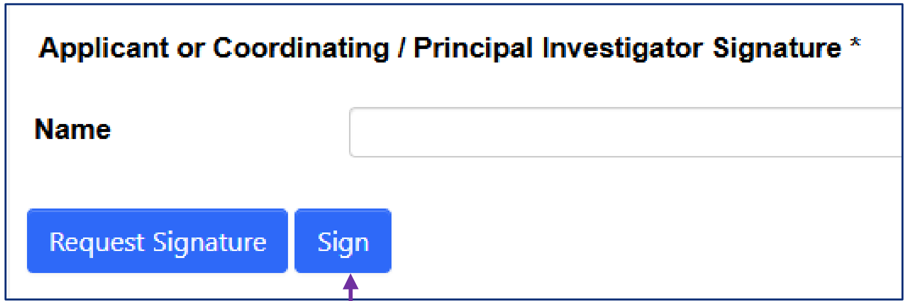
When an electronic signature is requested or applied, all form fields are locked (except **Request Signature** and **Sign** buttons). No further information can be entered – only additional signatures can be requested or applied. Ensure all fields are completed before requesting electronic signatures or signing electronically. (The **Completeness Check** process will enforce this requirement.)
Unlocking the form will invalidate all requested and applied signatures.

Important! On some forms, the signature sections, containing updateable fields and the signature buttons, are contained in repeatable sections. Once the form is locked, you can still create another occurrence of the signature section. **DO NOT DO THIS!**
If you create another occurrence, you will not be able to complete the updateable field, because the form is locked, and you will not be able to submit the form, because the field has not been completed. Hence, you will need to unlock the form – which will cancel the signature requests.

To send a request for an electronic signature:

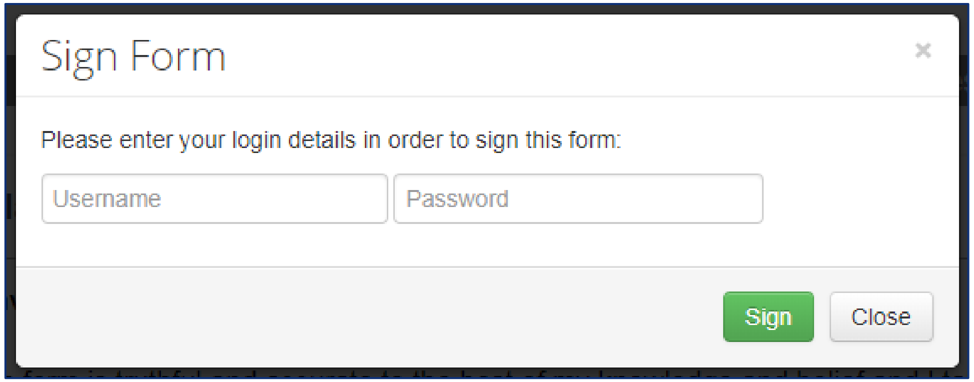
- Click the **Request Signature** button in the signature question
- Enter the ERM email of the signatory and an explanation if you wish. An email will be sent to the signatory.

If the signatory does not have an ERM account, you will need to ask them to create their account. When they have an ERM account, you can then request a signature from them.



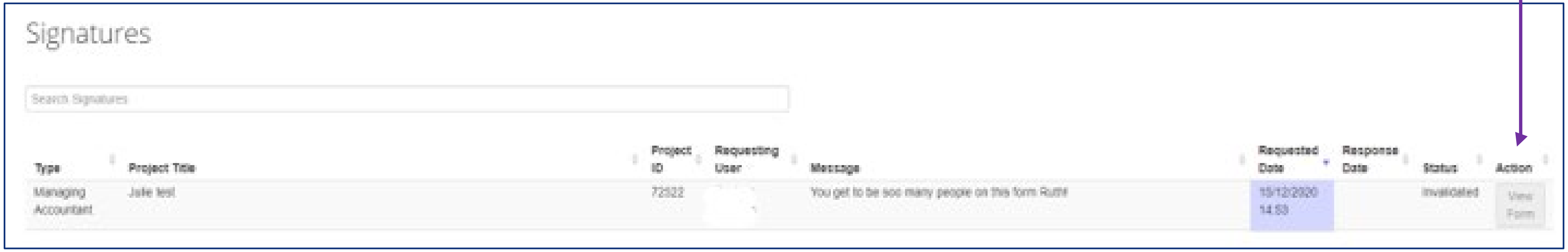
To sign the form directly:

- Click the **Sign button** in the signature question
- Enter your ERM username and password, then click Sign.



If you receive a signature request, click the link in the email to login to ERM, and access the **Signatures tile** in your Work Area.

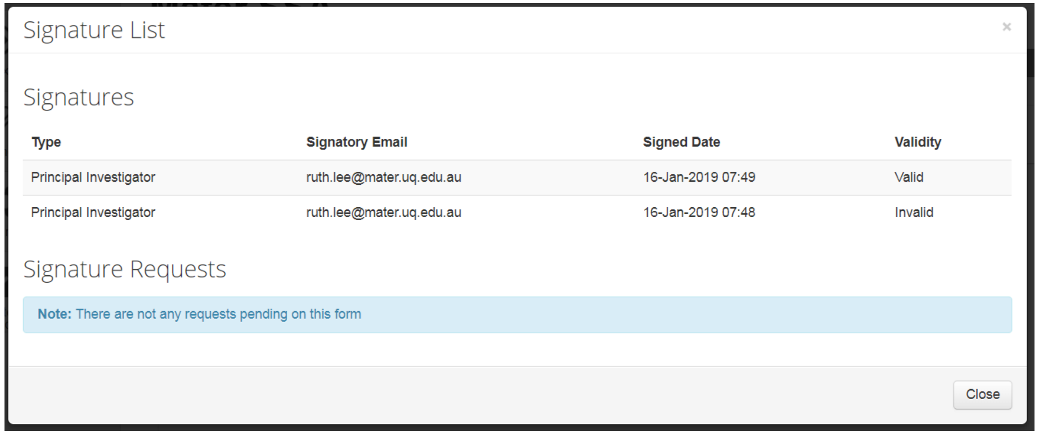
The **Signatures tile** provides a list of signature requests **sent to you** and their associated status.
Locate the required project in the list and click **View Form**. This will take you to the form.



You now have action options to **Sign** or **Reject**.
Enter your ERM username and password and click Sign or Reject. If you choose to reject, a field is provided to enter a reason.

Hot tip! Use the Signatures tile to confirm you have responded to all signature requests.

To view signatures collected, signatures requested and their associated statuses, click the **Signatures** action within the form, or the **Signatures** tab.

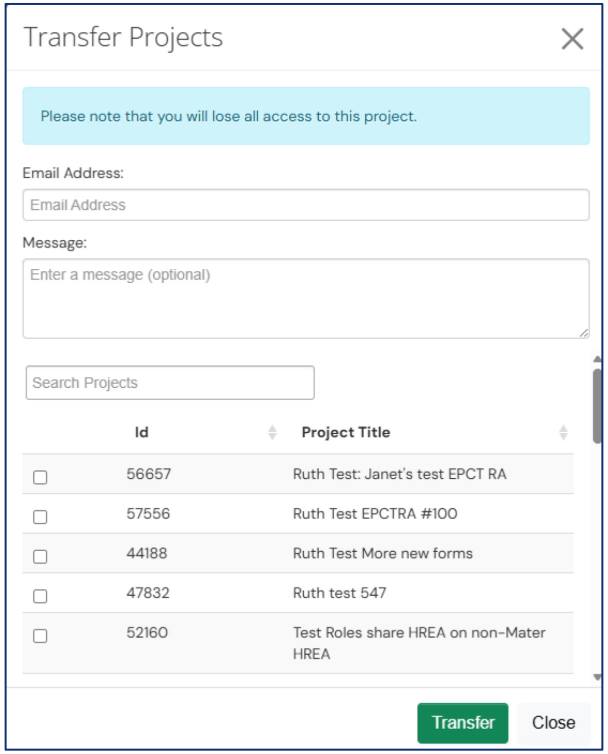


To **cancel** a request for an electronic signature:

- Click on the form in the project tree
- Click the Signatures tab
- Locate the required signature request
- Click Cancel.

Note: This will not invalidate any other signatures or signature requests and will not unlock the form.

Transfer ownership of projects



As the Project Owner (the person who created the project) you can transfer ownership of projects to other ERM users. For example, if you are leaving the project you will need to transfer ownership of the project in ERM to someone else.

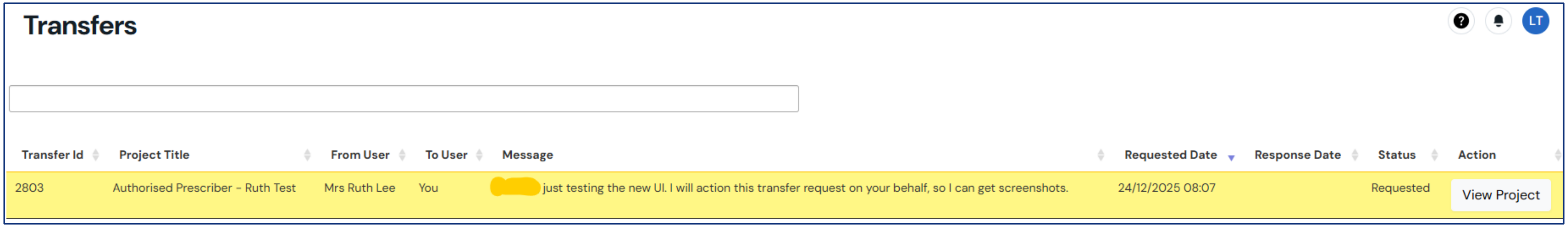
When you transfer the project, you lose access to that project – unless the new owner shares the forms with you.

To transfer a project, in the Work Area click the **Transfer** action.

Enter the email address of the person to whom you are transferring, type a message if you wish, select the project/s that you wish to transfer to them, then click **Transfer**. This will send a **Transfer Request**.

When you receive a Transfer Request, click on the link in the email to login to ERM and access the Transfer tile in your Work Area.

Click **View Project** to view the project in detail.



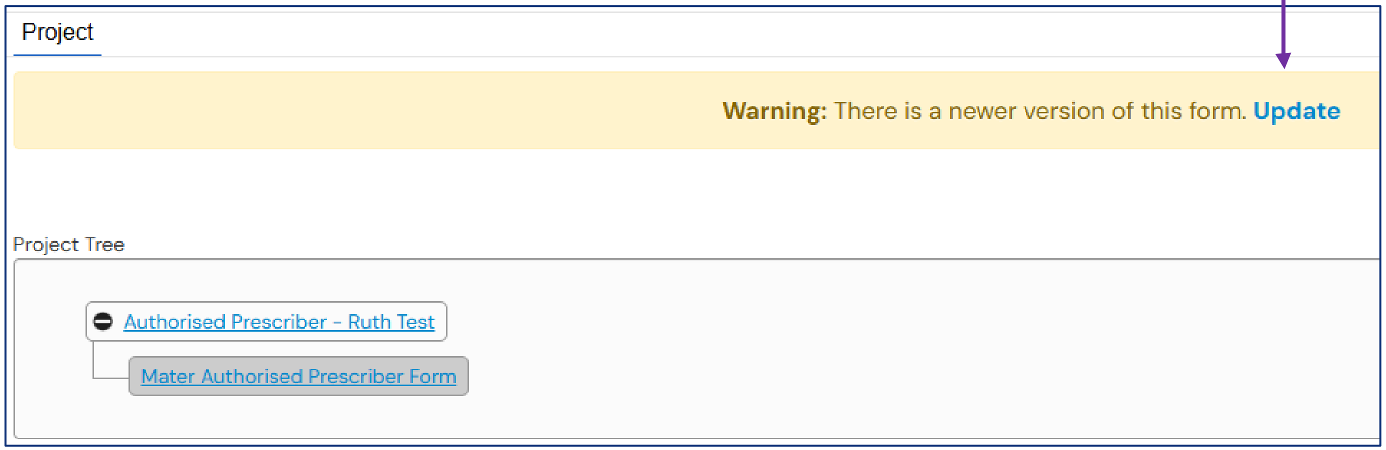
Click the appropriate action, either **Accept Transfer** or **Reject Transfer**, and confirm the action.

If you accept the transfer, you will now be the owner of the project and can provide access to other users. The previous owner will lose all access to the project.

Update projects to access the latest version of forms

As a project owner, you will need to update projects or forms following re-publishing of forms by the ERM administrator, to ensure the latest version of forms are used in the project. Forms are re-published when changes have been made to improve their functionality. Questions may be added, changed, or removed.

When a form needs to be updated, a message will appear near the top of the page when you have selected the project. The message advises that there is a newer version of the form available. If you are the project owner, you can click Update. If you are not the project owner, the message advises you to contact the project owner to perform the update.



Updating a project has the following effects. It will:

- make the latest version of all forms available to the project
- unlock unsubmitted forms that are locked by electronic signature requests
- invalidate electronic signatures and signature requests on unsubmitted forms.

Before updating forms within a project, the project owner should:

- Always check for unsubmitted forms in the project.
  - **Hot Tip!** To do this quickly, click the **<** on the left of the project title in the Work Area to expand the list of forms within the project and show the status of each form. It requires a quick scan looking for 'Unsubmitted' or 'Further info request' statuses.
- Open unsubmitted forms to check if they are locked.
  - If a form is locked, if possible, delay updating the project until the form has been submitted.
  - If an unsubmitted form is locked and the project is updated, then the electronic signatures and signature requests will be invalidated and will need to be requested again. Refer to the Electronic signatures chapter for further information regarding signatures.

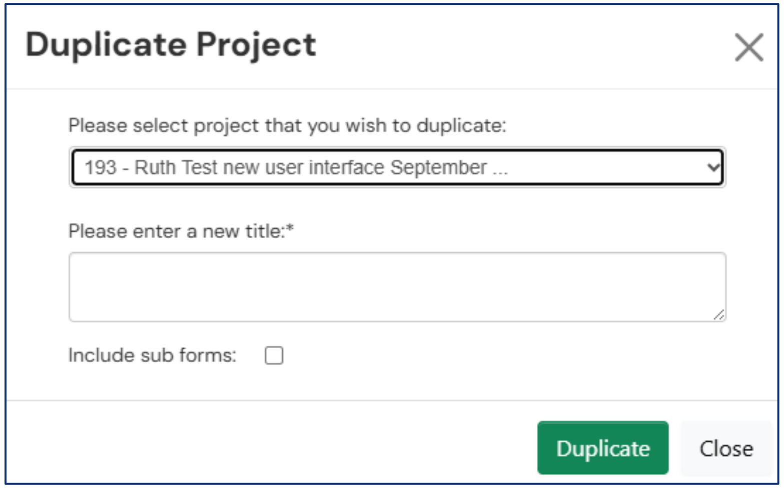
To update the forms in the project, click the blue **Update** button in the message at the top of the screen. The update may take several minutes to complete in large projects.

Duplicate projects

You can duplicate a project. This will create a new project containing the same forms as the project that you have duplicated.

The forms will contain the same information entered on the original forms. They will have a status of "Not submitted".

Documents from the original forms are **not** included.



Appendix A – Main forms

Form name	Review Reference Identifier	Purpose - use this form for …
HREA (Human Research Ethics Application)	HREC	Human Research Ethics applications which are not a Quality Assurance Activity or a research activity exempt from HREC review.
Mater Quality Assurance (QA) Projects and Case Reports	QACR	Quality assurance projects and case reports that are not research
Research Exempt from HREC review	EXMT	Research projects that are exempt from HREC review
MDF (Minimal Dataset Form)	MDF	For studies reviewed by a HREC that does not use ERM and require submission of an SSA to the Mater Research Governance Office, or SSA's for other study sites.
Authorised Prescriber	AP	Requesting Authorised Prescriber endorsement from the MML HREC.
Honours Student Project Application	HONSTUD	Applying for approval for an Honours Student Project that requires HREC review.

Appendix B – Mater subforms

Subform name	Related main form	Review Reference Identifier	Purpose - use this form for …
Site-specific Assessment	HREA, MDF	SSA	Site-specific assessment of projects involving humans and/or biospecimens
Amendment	HREA, MDF	AM	Advising of a change to the project (e.g., change to protocol or study team)
Progress and Final Report	HREA, MDF	PRGRPT, FINRPT	Submitting an annual progress or final report
Annual Safety Report	HREA, MDF	ASR	Submitting an annual safety report [1]
DSMB Recommendations	HREA, MDF	DSMB	Submitting DSMB recommendations or outcome letters [1]
Deviations and Breaches	HREA, MDF	DVBRE	Notifying of deviations, suspected breaches and serious breaches [1]
Significant Safety Issue	HREA, MDF	SSI	Notifying of urgent safety measures, temporary halts or early terminations [1]
SAE/SUSAR/USADE	HREA, MDF	SAEI	Notifying Mater RGO of a serious adverse event (SAE), serious adverse reaction (SAR), serious adverse device effect (SADE), suspected unexpected serious adverse reaction (SUSAR) or unanticipated serious adverse device effect (USADE). [1]

[1] Refer to Clinical Trials Safety Reporting Framework (MPPL-07986) for details of safety reporting requirements.

Authorised Prescriber Amendment	AP	APAM	Advising of a change to the Authorised Prescriber endorsement
Authorised Prescriber Report	AP	APRPT	Submitting a regular report regarding the Authorised Prescriber endorsement

Appendix C – Pre-defined permissions of Mater roles

On main forms

Role	Permissions
Main Forms (read only)	Allows collaborator to read the main form only
Main Forms (read/subforms)	In addition to reading, allows the collaborator to create subforms
Main Forms (read/write/subforms/share)	In addition to reading and creating subforms, allows the collaborator to update and share the main form, and receive notifications
Main Forms (read/write/subforms/share/submit)	In addition to the above, allows the collaborator to submit the main form
Full Project (read only)	Allows collaborator read only access to the main form and all subforms
Full Project (read/subforms)	In addition to reading all forms, allows the collaborator to create subforms and receive notifications
Full Project (read/write/subforms/share)	In addition to the above, allows the collaborator to update all forms and share all forms
Full Project (read/write/subforms/share/submit)	In addition to the above, allows the collaborator to submit all forms.

On Mater subforms

Role	Permissions
Subforms (read only)	Allows collaborator to read all subforms and read the main form
Subforms (read/subforms)	In addition to reading, allows the collaborator to update all subforms, read the main form, create subforms from the main form and receive notifications
Subforms (read/write/subforms/share)	In addition to the above, allows the collaborator to share all subforms
Subforms (read/write/subforms/share/submit)	In addition to the above, allows the collaborator to submit all subforms

On SSAs

Role	Permissions
SSA Signatory	Allows the specified signatory to read the Mater SSA and read the main form. This includes reading documents attached to these forms