mater research

Ethics Review Manager (ERM)

User Guide for Researchers

mater.org.au

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 Office and the Mater Research Governance Office.

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 place, within ERM.

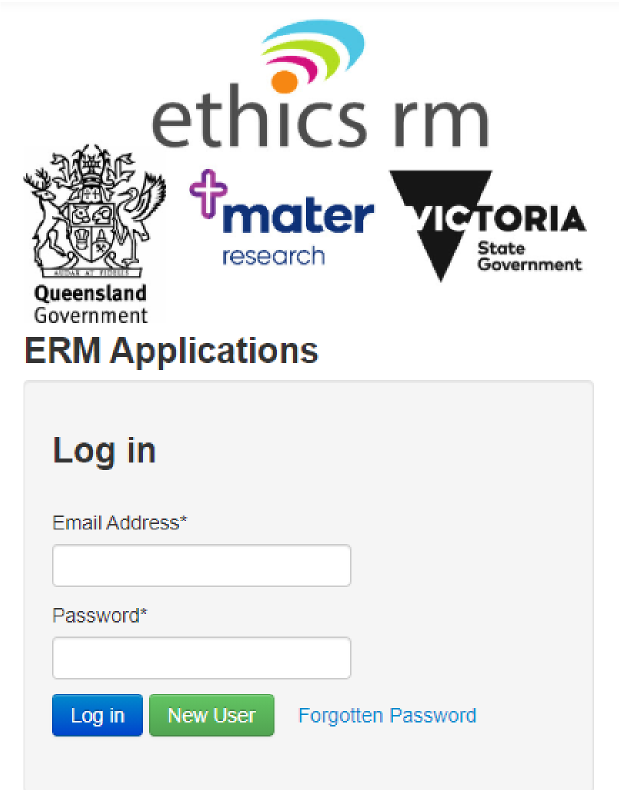
All project forms and documents that you submit to these offices are stored within ERM, so they are easily referenced and organised.

Create a new account in ERM

- If you submitted an online ethics application prior to 2018, it is possible there is already an ERM account in your name. Contact the Infonetica Help Desk and ask them to check.
- If you already have an account, they will provide you with the login name.
- Go to au.forms.ethicalreviewmanager.com
- Enter your login name then click on **Forgotten Password** to reset your password.
- If you do not have an ERM account, 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.

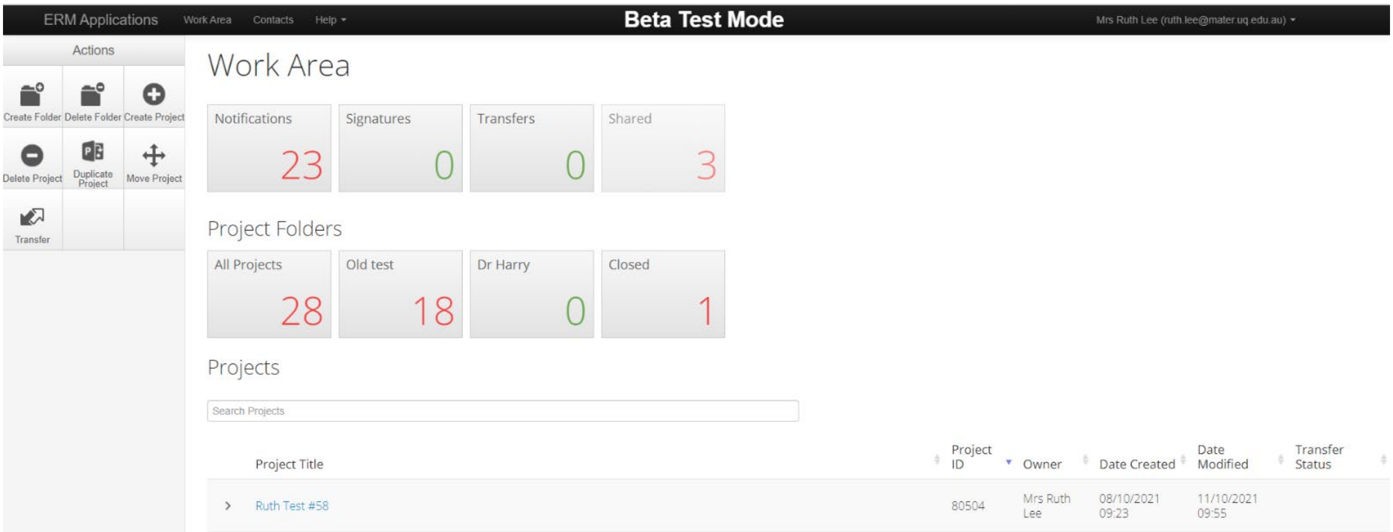
Login to ERM

- 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 on the **Forgotten Password** to reset your password.
- If you have trouble logging in, email the Infonetica Help Desk.

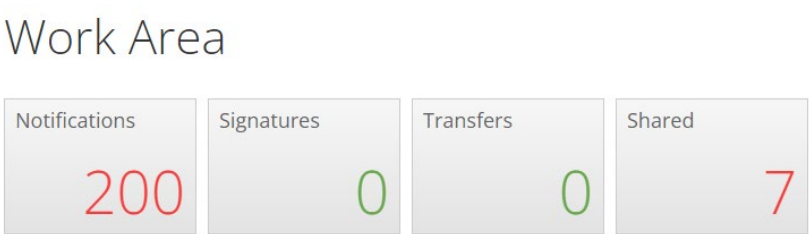


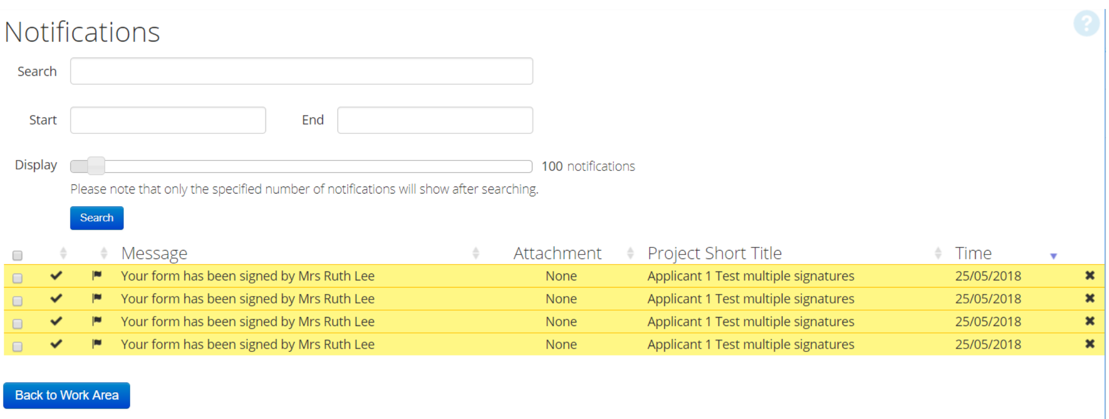
Work Area

- This is your control dashboard.
- The Help dropdown menu contains a list of FAQs and responses. It is recommended that you read the FAQs before beginning work in ERM.
- The 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 have not been viewed or require action by you.
- Projects that you can access are displayed in the Projects list. Click on the > on the left of a project to expand the project and view the forms in the project.
- The Actions on the left allow you to perform a range of actions.
- Click 'Work Area' in the black banner to return to this Work Area.



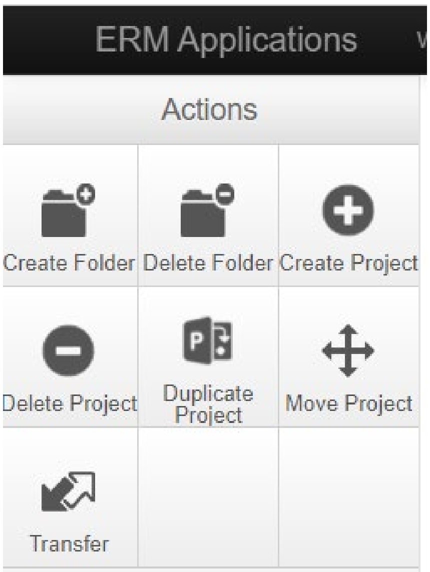
Tiles in the Work Area





- The Notifications tile shows the number of unread notifications in red. Notifications are internal ERM messages.
    - Click on the Notifications tile to view your notifications.
    - 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.*
- The Signatures tile contains requests for your electronic signature.
- The Transfers tile contains the projects that have been transferred to you and transferred by you.
- The Shared tile contains the forms that have been shared with you.

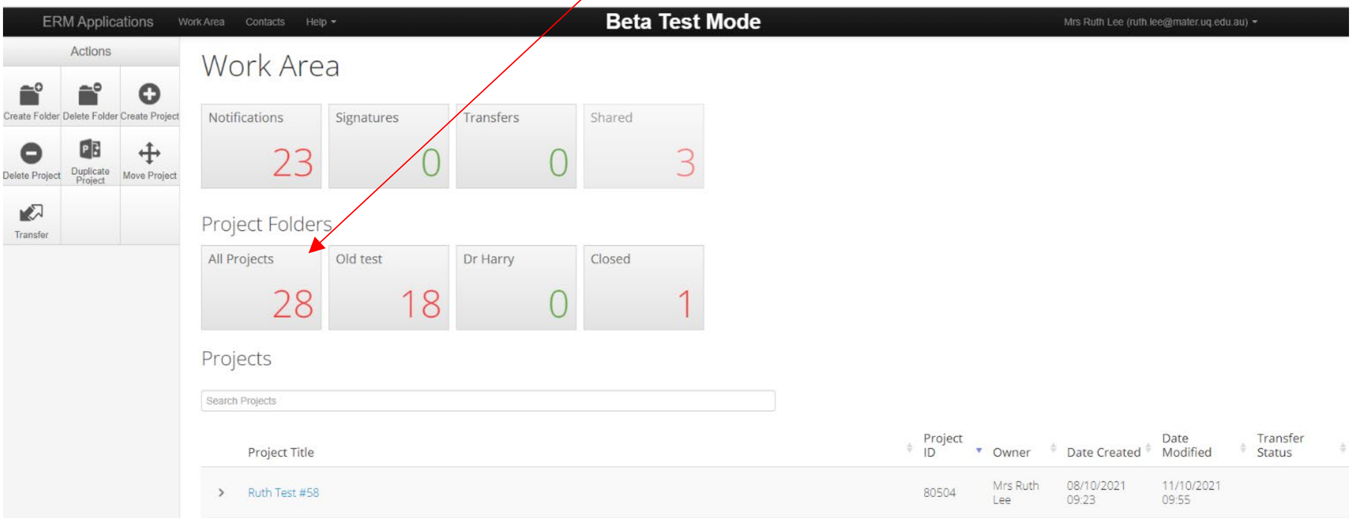
Actions in the Work Area



Actions allow you to perform a range of actions:
- Create Folder – create folders to organise your projects
- Delete Folder – delete folders that you have created. Ensure you move all projects out of a folder prior to deleting it
- Create Project – create a new project
- Delete Project – delete a project that does not contain 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

Search for an existing project

To search for existing projects, use the Search Projects field above the list of Projects, or if you have created folders, then click into the **All Projects** folder and search from there.

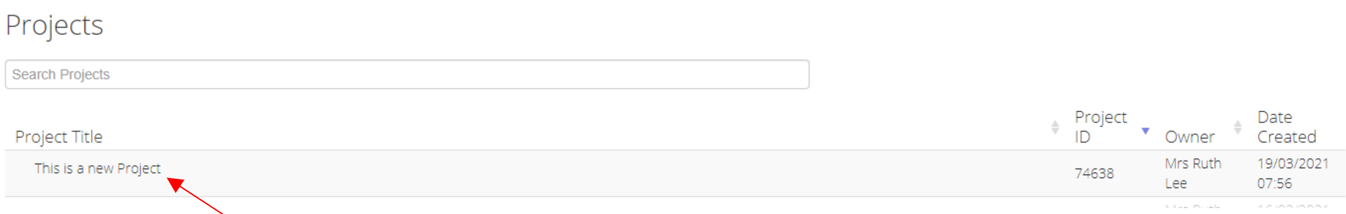


- Your project may be in ERM, but you may not be able to see it if you were not the original applicant or if the Project Owner has not yet shared required forms with you in ERM.
- Consult with your study team members to see if they have access to the project in ERM. If so, then request that they give you access to relevant forms, using the Roles or Share actions. This will give you access to view the required forms in the project.
- 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 reference. They can search for your project. If it is in ERM, they can tell you who can give you access to the project.

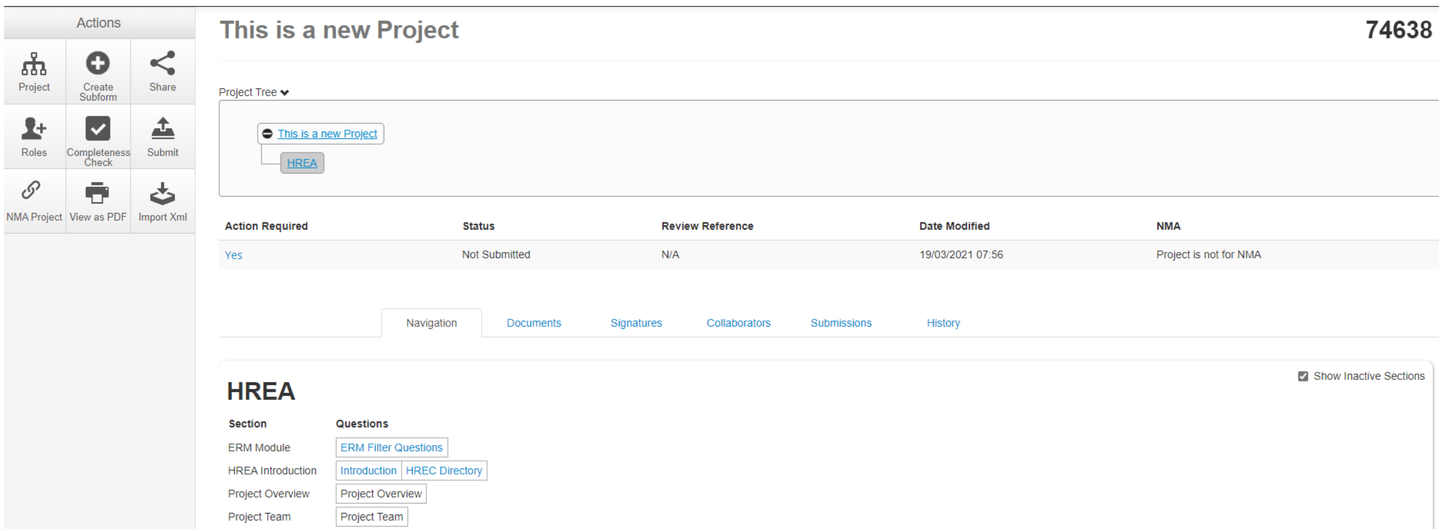
Create a new project

- In ERM, **projects** are comprised of one main form and zero, one or more subforms.
- To create a new project, click on the **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. Ensure it is correct as it cannot be changed in ERM after the project has been approved.
- 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.



The **Project Tree** displays all forms created in this project that you have been given access to.

Action Required indicates if any action is pending on the form. Click on '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.

Status displays the current status of the form. It will change as the form moves through the review phases.

Review Reference will be allocated when the form is submitted.
It will be in this format, AAAA/MMM/99999 (Vx), where:

- AAAA is the form identifier (refer to Appendix A for these values)
- MMM identifies the reviewing team (MML – Mater Misericordiae Ltd HREC, MRGO – Mater Research Governance Office)
- 99999 is the Project ID
- Vx identifies the version of the submission.

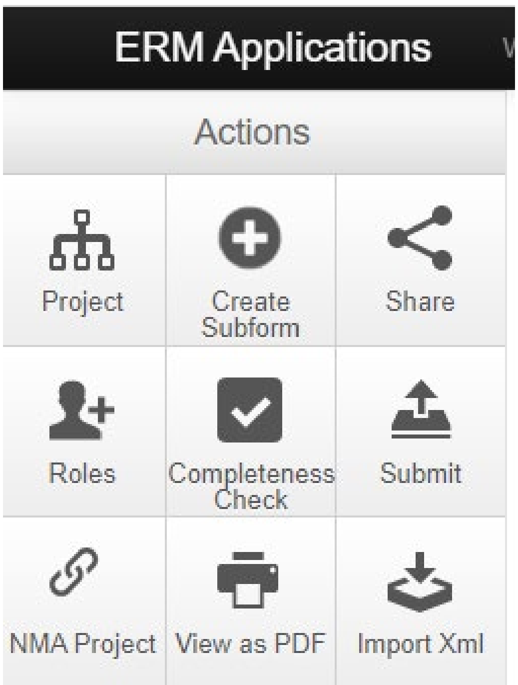
NMA indicates if the project is conducted across multiple sites and needs to be shared with other sites in ERM ('Project is for NMA') or if it is only to be conducted at a single site ('Project is not for NMA').

The **row of tabs** shows information that will compile 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.
    - If they were given access using **Share**, you may adjust their Form access permissions from the Edit Permissions button.
    - If they were given access using **Roles** (the preferred method), their permissions may only be edited using the **Roles** action. (Refer to Access to projects and forms chapter.)
- **Submissions** – displays all submissions of this form (you may need to submit more than once to provide further information in response to a review)
- **History** – displays all events occurring on the form.
    - ***Hot Tip!*** *Important items such as Approval and Authorisation letters are available as downloadable attachments within the History. Simply locate the relevant event within the history (e.g. "The Mater RGO has authorised your study") and click the* ***Download*** *button.*

The lower section of this page displays sections of the form. Those 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 in a project

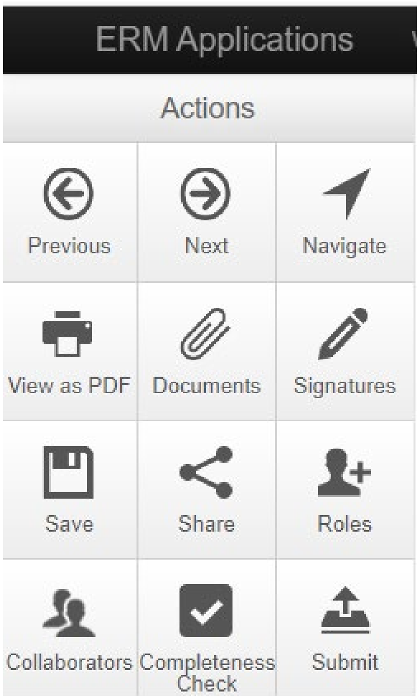


These **Actions** are displayed when you click on a project:

- **Project** – takes you to the highest level in the project, display the Project Tree and all project level information, including forms that you may not have access to.
- **Create Subform** – creates a subform of the current form (refer to Appendix B).
- **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.
- **Completeness Check** – checks that all mandatory questions have been answered on the form before requesting signatures and submitting.
- **Submit** – submits the form. If mandatory questions have not all been answered, you will not be able to submit the form.
- **NMA Project** – allows you to change the NMA status of the Project. By default, this is set to "Project is not NMA". If unsure, the HREC or Research Governance Office can advise and adjust this setting.
- **View as PDF** – generates a pdf of the form, which can be printed or saved.
- **Import XML** – this action is only available on the HREA. It allows you to import the XML version of a HREA created in the NHMRC HREA portal.

Complete a form and submit

Click on a blue question to access the form. These are the **Actions** you can now perform:



- **Previous** and **Next** – use these to navigate through the pages in the form. Changes will be saved as you move to a different page. Previous and Next buttons are also located at the bottom of each page of the form.
- **Navigate** – takes you back to the Project Tree where you can access the sections of the form directly. All changes will be saved when you navigate out.
- **View as PDF** – generates a pdf of the form in a new browser tab, which can then be viewed, printed, or saved.

- **Documents** – allows you to view all documents uploaded into the form.
- **Signatures** – lists electronic signatures collected and the status of signature requests. Note that when an electronic signature is requested, all fields on the form are locked (except signature Request and Sign buttons) so you cannot enter further information. You can **unlock** the form after it has been locked, but this will invalidate all signature requests and electronic signatures that have been collected. Refer to the Electronic signatures section for further details.
- **Save** – saves the latest changes to the form.
- **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.
- **Collaborators** – displays the Project Owner, Form Owner, and people who have been given access to the form.
- **Completeness Check** – checks that all mandatory questions have been answered on the form. Use this before signing or requesting electronic signatures.
- **Submit** – submits the form. If mandatory questions have not all been answered, you will not be able to submit the form.
- **Unlock** – use this action to unlock the form if fields need to be updated after the form has been locked. Note that all electronic signatures and signature requests will be invalidated when the form is unlocked. Refer to the Electronic signatures section for further details.

Electronic signatures

Signatures on all Mater ERM forms are collected electronically.

When an electronic signature is requested, all fields on the form are locked (except **Request Signature** and **Sign** buttons) so you cannot enter further information. You can only request other signatures or sign electronically. Ensure all fields are completed before requesting electronic signatures or signing electronically. (The **Completeness Check** process will force this requirement.) You can unlock the form once it becomes locked, but this will invalidate all signature requests and electronic signatures that have been collected.

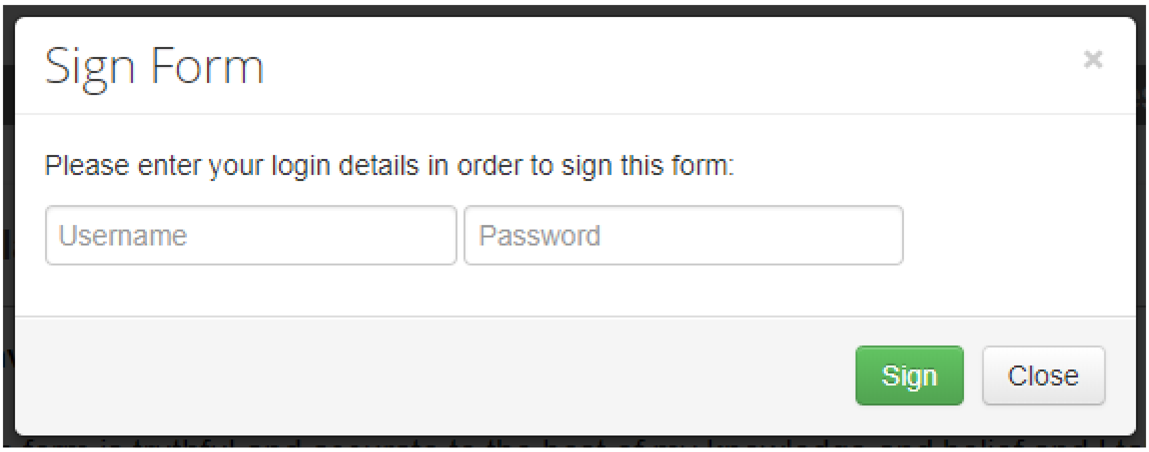
To send a request for an electronic signature:

- Click on the **Request Signature** button
- 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.

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 will still be able to 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.

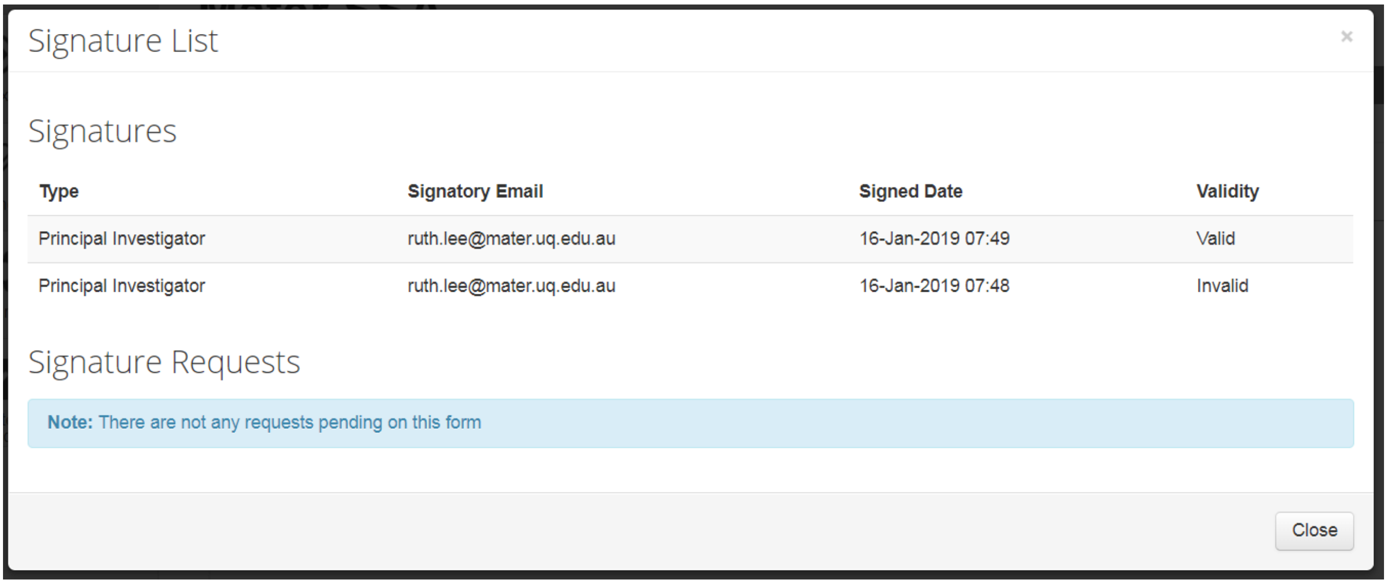
To sign electronically:

- Click on the **Sign button** (if you have accessed the form from the Projects list) or the **Sign action** (if you have accessed the form via a signature request).
- Enter your ERM username and password:

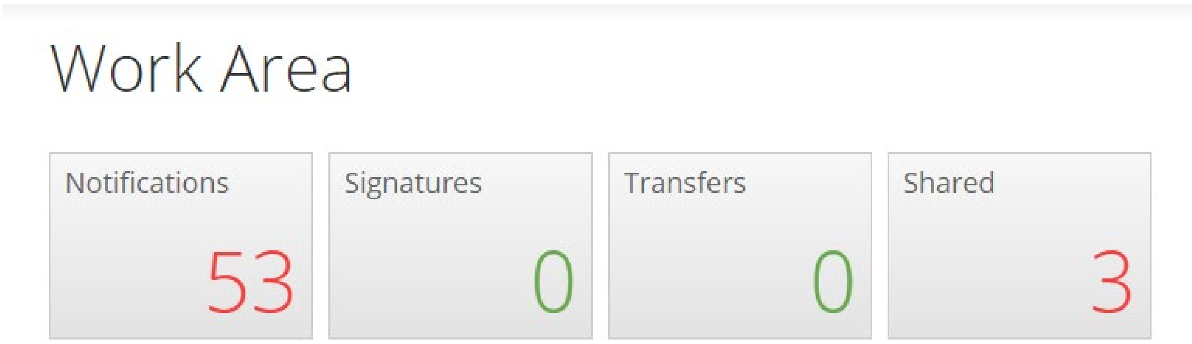


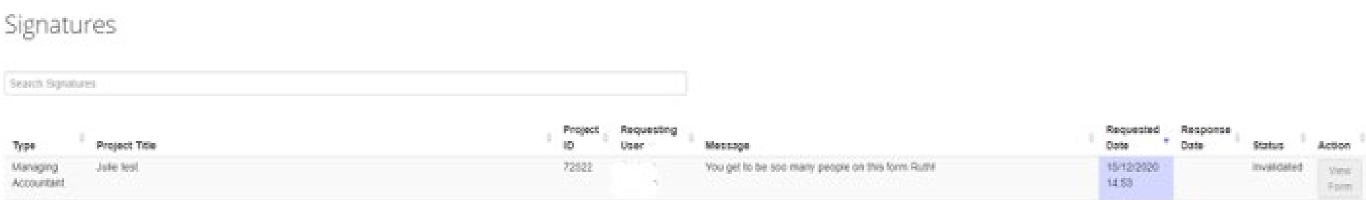
If you have received a signature request, you have the options to **Sign** or **Reject**. If you choose to reject, a field is provided to enter a reason if you wish.

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



The **Signatures tile** in your **Work Area** provides a list of signature requests sent to you and their associated status.





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

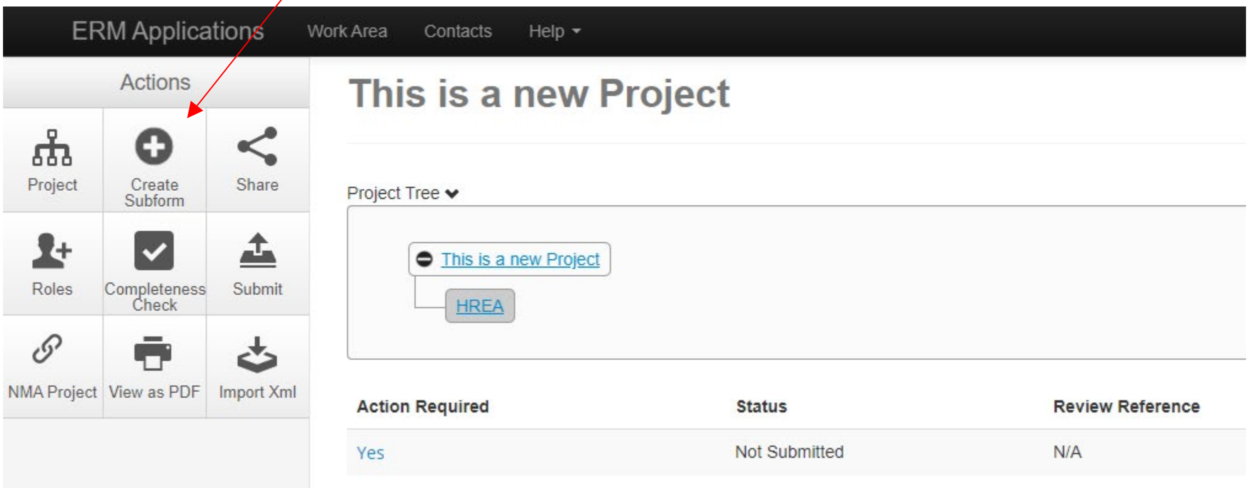
- Click on the form in the project tree
- Click on the Signatures tab
- Locate the required signature request
- Click Cancel.

Note this will <u>not</u> invalidate any other signatures or signature requests and will <u>not</u> unlock the form.

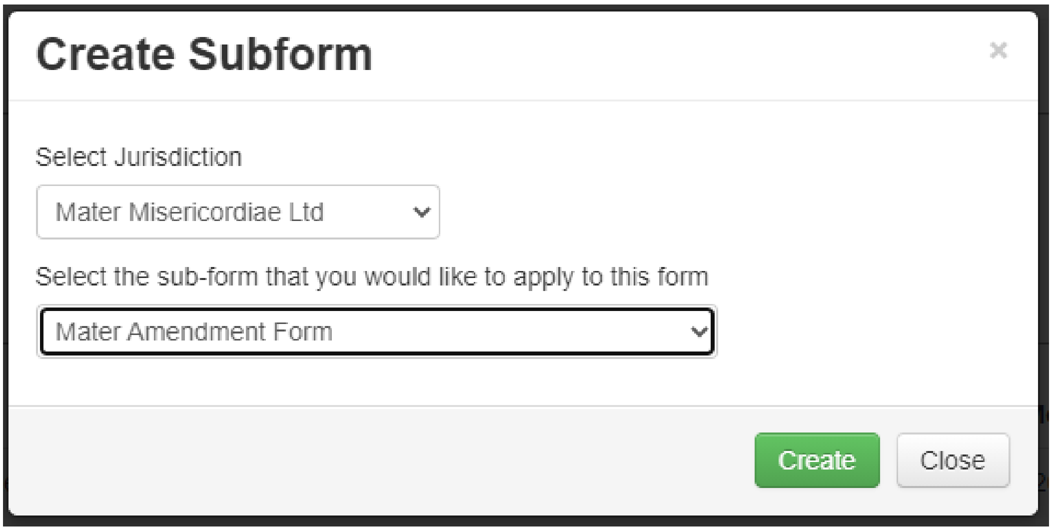
Create a subform

The Mater Site-Specific Assessment form, Amendment form, Progress and Final reports, SAE/SUSAR/USADE form, and the safety reporting forms are all subforms of the HREA.

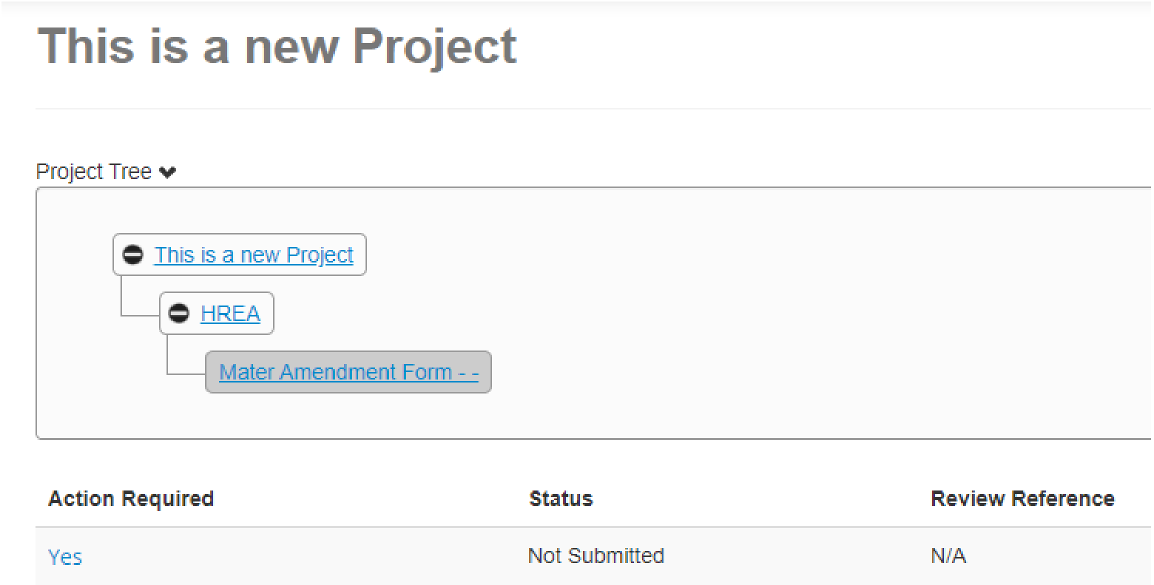
- To create these subforms, ensure the HREA is highlighted in the Project Tree then click on the **Create Subform** action.



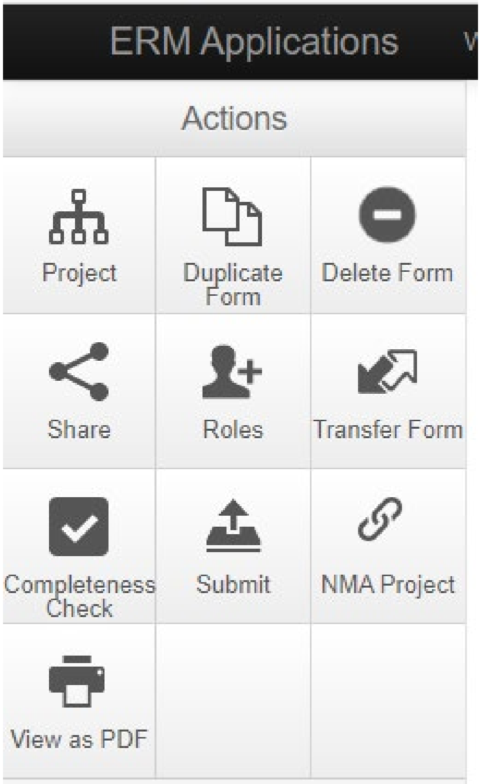
- Select the jurisdiction and the subform, then click **Create.**



- The subform will appear in the Project Tree.



- When clicked on a subform in the Project Tree, you have an additional option to **Delete Form**. Note that a form can be deleted up until it has been submitted. When the reviewing office begins processing the form (i.e. the status is changed), the form can no longer be deleted.

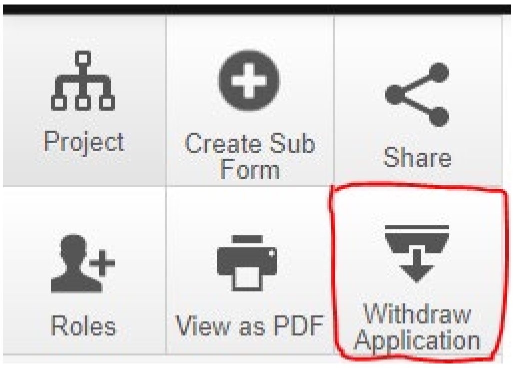


- Complete and submit the subform in the same manner as the Main Form.

Withdraw a submitted form

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

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



Access to projects and forms

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 created in the **Mater jurisdiction** 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 that appropriate permissions are allocated.

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

- Click on the project
- In the Project Tree, click on the **Main form** (the first form under the Project title e.g. HREA, MDF, or DM HREC MDF.)
- Click the **Roles** action
- Enter the 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 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 share with them.
- If you need to modify permissions given to a study team member, 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** that 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 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** that 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** that **SSA Signatory** access is recommended for signatories who may need to read documents attached to the main form and the SSA.

Note that 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.

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, use the **Collaborators** tab to Edit Permissions.

Forms returned for further information

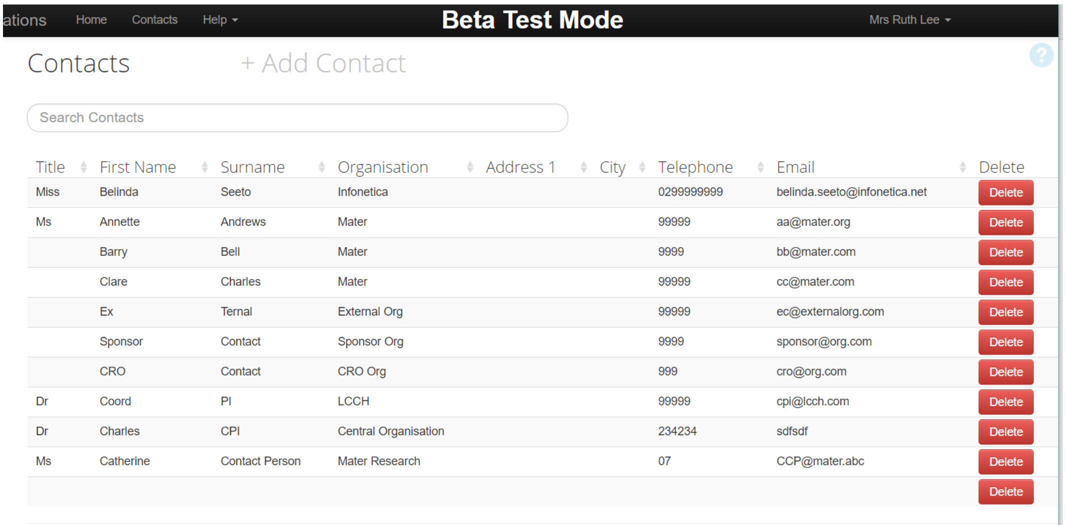
If the HREC office or RGO request further information from you, they may unlock the form so you can update and resubmit it. When this happens:
- You will receive a notification in ERM and an email from 'donotreply@infonetica.net', containing details of the request.
- The status of your submission will change to '**Further Information requested'** or something similar, depending on the form.

- Provide the requested further information, such as changing information in form fields or uploading new or replacement documents, collect the required electronic signature/s then click Submit to send it back to the administrators for continued review.

Contacts

You can keep your personal list of contacts in ERM.

- Click on the **Contacts** menu item in the top menu bar to add and update your contacts.

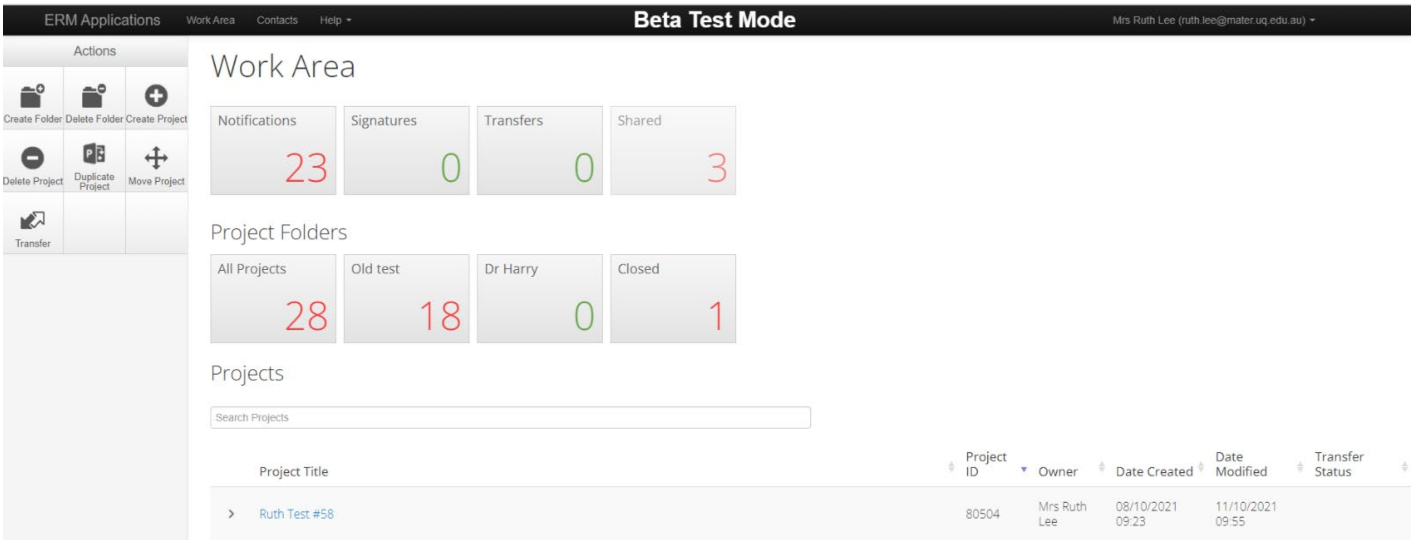


Title	First Name	Surname	Organisation	Address 1	City	Telephone	Email	Delete
Miss	Belinda	Seeto	Infonetica			0299999999	belinda.seeto@infonetica.net	Delete
Ms	Annette	Andrews	Mater			99999	aa@mater.org	Delete
	Barry	Bell	Mater			9999	bb@mater.com	Delete
	Clare	Charles	Mater			99999	cc@mater.com	Delete
	Ex	Ternal	External Org			99999	ec@externalorg.com	Delete
	Sponsor	Contact	Sponsor Org			9999	sponsor@org.com	Delete
	CRO	Contact	CRO Org			999	cro@org.com	Delete
Dr	Coord	PI	LCCH			99999	cpi@lcch.com	Delete
Dr	Charles	CPI	Central Organisation			234234	sdfsdf	Delete
Ms	Catherine	Contact Person	Mater Research			07	CCP@mater.abc	Delete
								Delete

- In addition to the above method, a more convenient method of adding contacts to your list is from within the forms on the **Contacts** questions.
- When completing contact questions in forms, after entering details for a contact for the first time, click **Add to Contacts** and 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 entering them again.
- The mandatory fields are highlighted with an *.
- Not all contact fields are displayed in every contact question.

Create and delete folders

- You can create folders to customise and organise your Work Area.
- You can drag and drop projects from the main Projects list into your folders or use the **Move Project** action to move projects between folders.
- The **All Projects** folder contains all projects that you can access.
- You can also rename and delete folders.

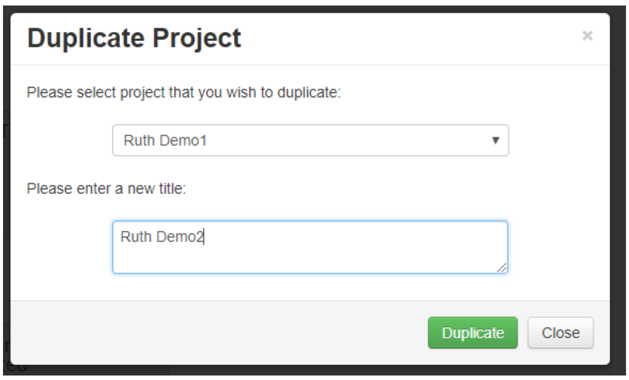


Delete forms and projects

- You can delete subforms - if they are not submitted and are unlocked.
- 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 have created a 'dummy' project for learning purposes. Subforms must be deleted first then the project can be deleted. This also deletes the main form.

Duplicate projects

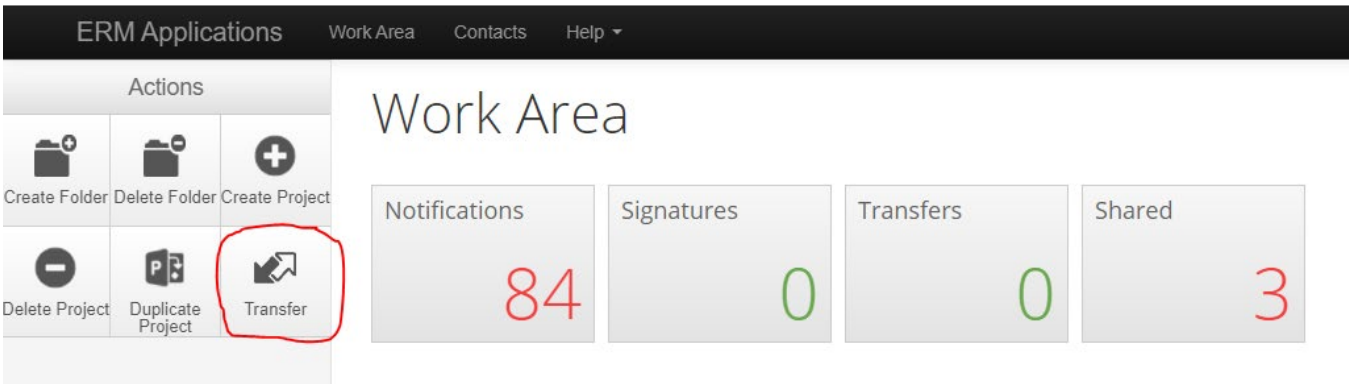
- You can duplicate a project. This will create a new project containing the same forms as the project that you have duplicated.
- The forms will contain the same information entered on the original forms. They will have a status of "Not submitted".
- Documents from the original forms are <u>**not**</u> included.



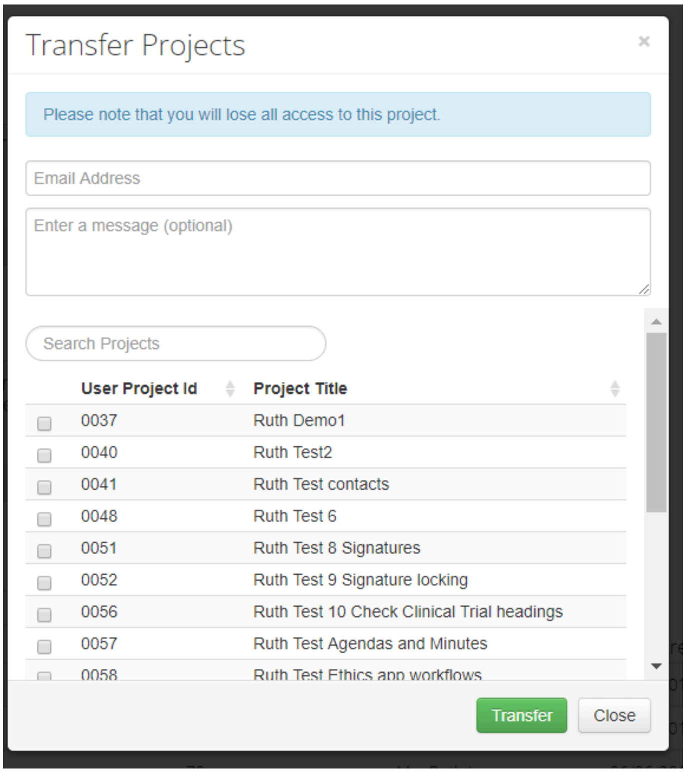
Transfer ownership of projects

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 study you will need to transfer ownership of the project to another person on the study.
When you transfer the project, you lose access to that project – unless the new owner shares the forms with you.

To transfer a project, click the **Transfer** action, which will send a **Transfer Request**.

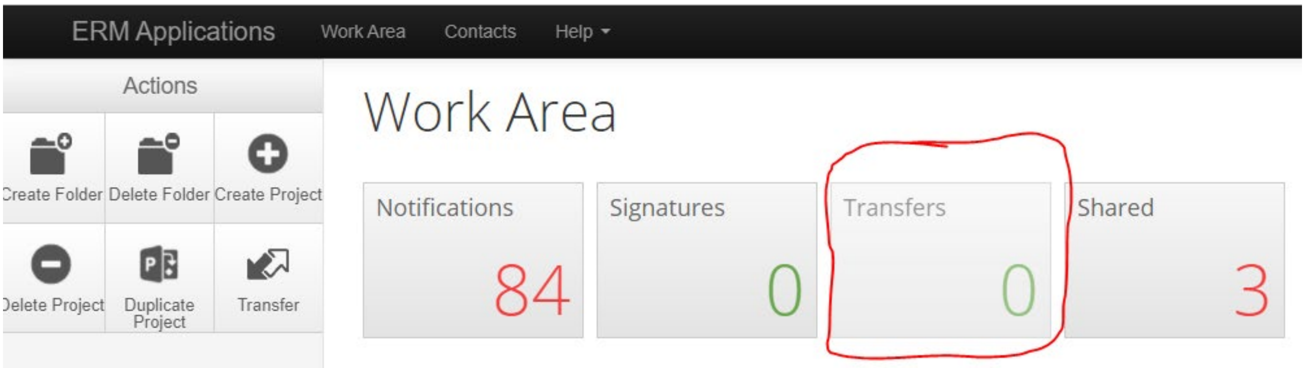


Enter the email address of the person you are transferring to, type a message if you wish and then select the project/s that you wish to transfer to them.

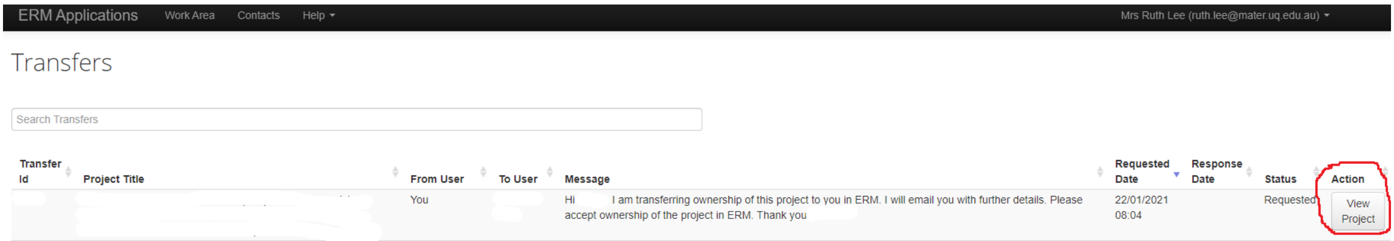


The recipient will receive an email containing a link to the ERM login page and advising them to **Accept** or **Reject** your transfer request.

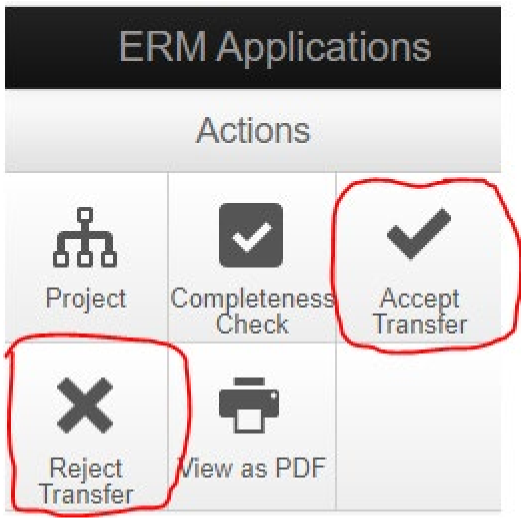
To action a transfer request, click on the **Transfers** tile in the Work Area.



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



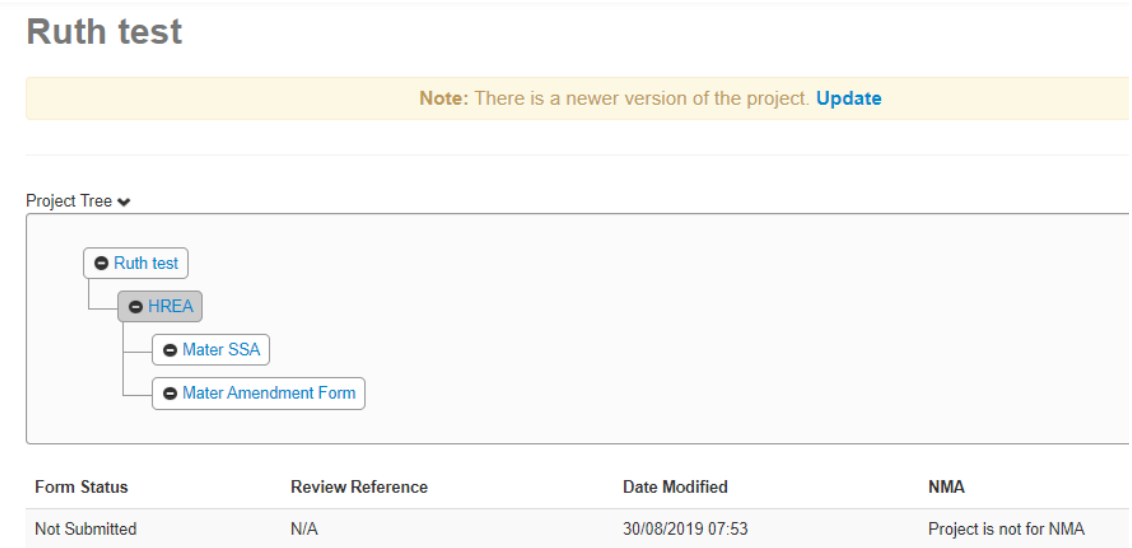
Click the appropriate action, either **Accept** or **Reject**, and confirm the action.



You will now be the owner of the project and can provide access to other users.

Update projects to access the latest version of forms

As the Project Owner (the person who created the project) you will need to update projects 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 them to improve their functionality and to fix errors. Questions may be added, changed, or removed.



When a project 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 project available.

Updating a project has the following effects:

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

Before updating 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 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 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.

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.
Early Phase Clinical Trial Risk Assessment	EPCTRA	Submitting a Risk Assessment to the RGO for expert advisor review of early phase clinical trials.

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 studies involving humans
Biomedical SSA	HREA, MDF	BMSSA	Site-specific assessment of studies involving human biospecimens
Waiver SSA	HREA, MDF	WSSA	Site-specific assessment of studies involving only data obtained from Mater records
Amendment	HREA, MDF	AM	Advising of a change to the study
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
DSMB Recommendations	HREA, MDF	DSMB	Submitting DSMB recommendations our outcome letters
Deviations and Breaches	HREA, MDF	DVBRE	Notifying of deviations, suspected breaches and serious breaches
Significant Safety Issue	HREA, MDF	SSI	Notifying of urgent safety measures, temporary halts or early terminations
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).

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 roles

On main forms:

- **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 the main form, 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 subforms:

- **Subforms** (read only) – allows collaborator to read all subforms and read the main form
- **Subforms** (read/write/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 SSA's:

- **SSA Signatory** – allows the specified signatory to read the Mater SSA and read the main form. This includes reading documents attached to these forms.