Ethics Review Manager (ERM)

User Guide for Researchers

Contents

Introduction

Welcome to ERM!

ERM (Ethics Review Manager) is now the only method for submitting Human Research Ethics applications, Quality Assurance/Exempt and Authorised Prescriber applications to the Mater HREC, Site-Specific Assessments to the Mater Research Governance Office, submitting Amendments and Reports to both offices and submitting Risk Assessments to the Early Phase Clinical Trials Expert Advisory Committee (EPCT EAC). These offices all use ERM to process your applications.

Queensland Health and Health Victoria are also using ERM 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 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 the Mater HREC, Mater Research Governance Office, EPCT EAC, Queensland Health and Health Victoria are stored within ERM, so they are easily referenced and organised.

Login to ERM

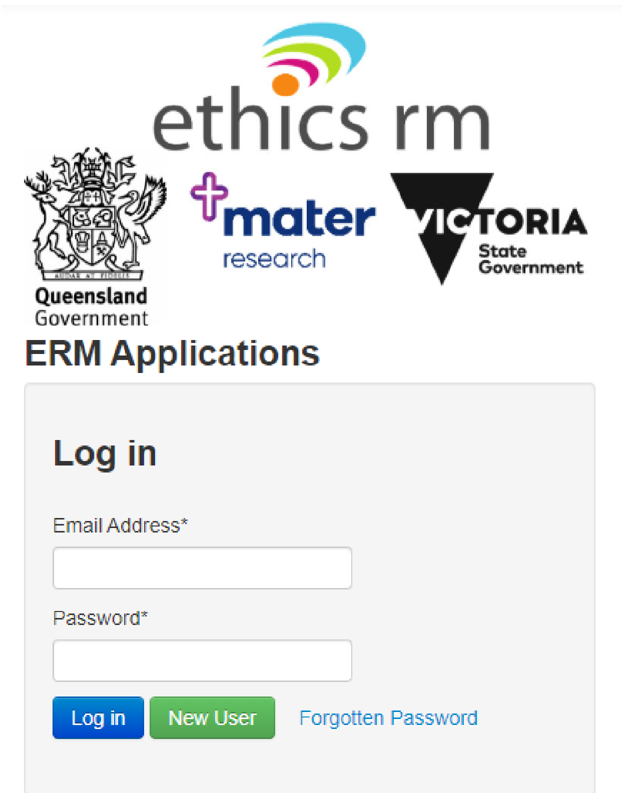
If you have used Online Forms previously to create and submit a HREA, then your ERM account will be created for you.

- Go to au.forms.ethicalreviewmanager.com
- Login using your Online Forms email address and password. If you can't remember your password, click on the Forgotten Password link on the login page. If you still have trouble logging in, email the Infonetica Help Desk.

Create a new account in ERM

- If you are not sure if you should have an ERM account, please contact the Infonetica Help Desk prior to proceeding.
- If you are advised to create your account:
  - Go to au.forms.ethicalreviewmanager.com

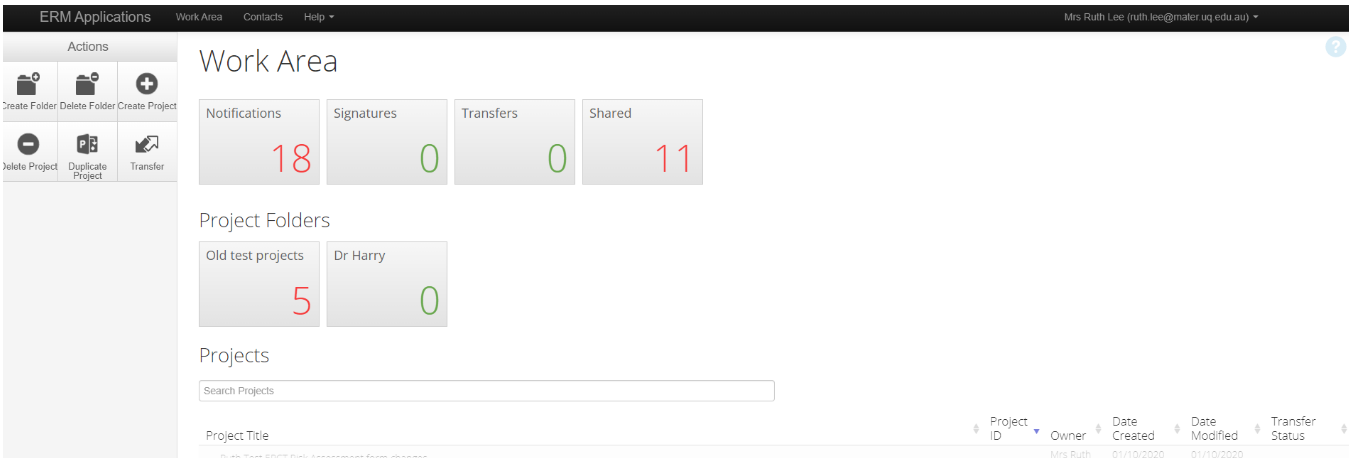
- Click on New User



- Enter your title, first and last names, organisation, email and password as a minimum, ensuring you enter your relevant email address – as this will be your login username and your correspondence address used by ERM. If you are a Mater staff member, please use your Mater email address.
- When you click Register, ERM will send you a confirmation email.
- You can now login to ERM on the au.forms.ethicalreviewmanager.com website.

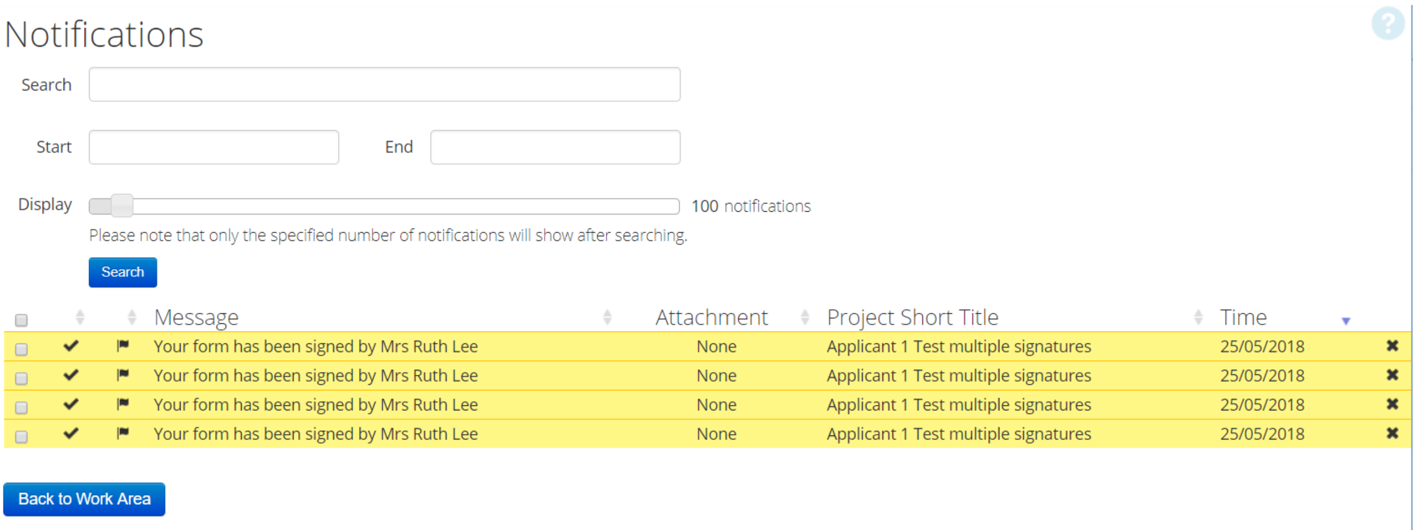
Work Area

- 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 General 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.
- Your Projects are listed in the Projects list.
- The Action tiles on the left allow you to perform a range of actions.
- Click 'Work Area' in the black banner to return to this Work Area.

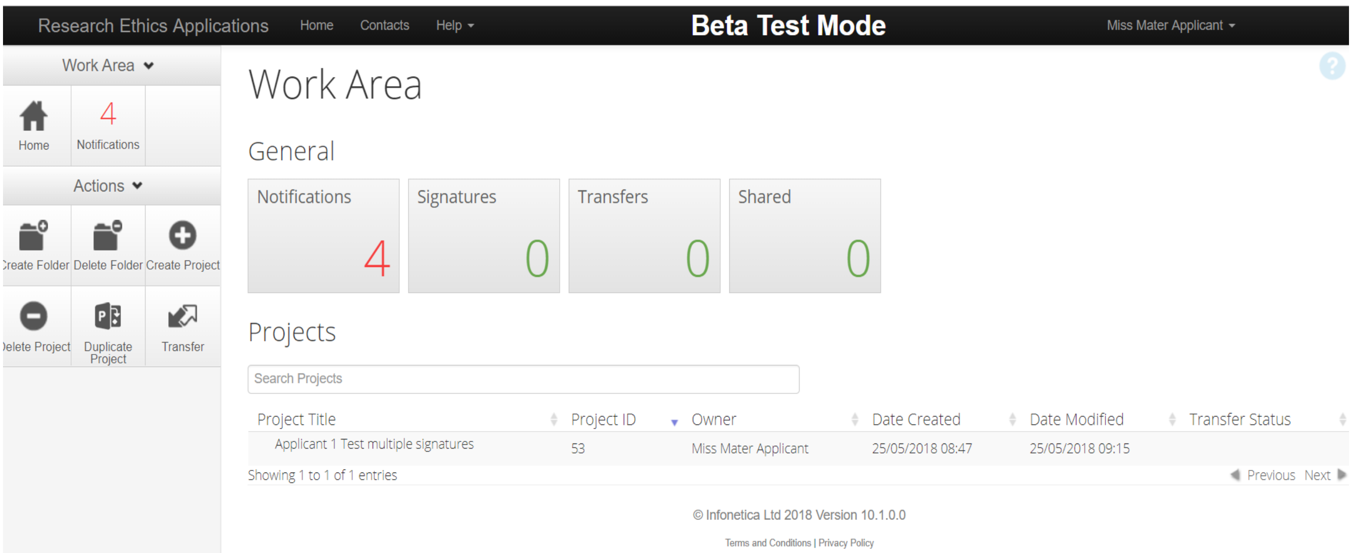


Notifications

- 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, RGO or EAC Administrators. Note that you will also receive an email when a response is required from you regarding your submissions.

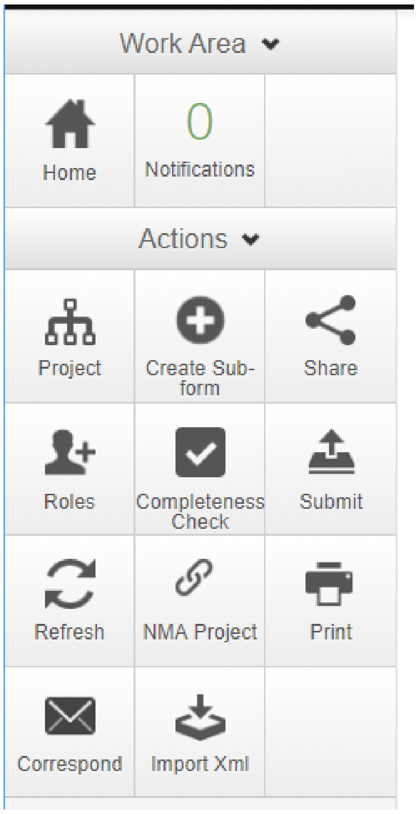


Other General tiles



- The Signatures tile will show requests for your electronic signature.
- The Transfers tile will show the Projects that have been transferred to you and transferred by you.
- The Shared tile will show the Forms that have been shared with you.

Action Tiles



The Action tiles allow you to perform the described actions:

- Project – this will take you back to the Project level and display the Project Tree
- Create Form – this creates another form at the same level as the current form
- Create Sub-form – creates a sub-form of the current form e.g. sub-forms of the HREC application include SSAs, Amendments, Progress and Final Reports, Safety reports
- Share – this allows you to share the current form with other users and set their permissions. You will need to do this to allow others to view or update the form.
- Roles – this allows you to apply a Role to other study team members, by setting their access permissions for multiple forms in the Project. The access permissions are pre-defined. Refer to the Sharing Forms paragraph for more details.
- Completeness Check – this will check that all mandatory questions have been answered on the form before trying to submit.
- Submit – this will submit the form. If mandatory questions have not all been answered, it will not allow you to submit.
- Refresh – to Refresh your screen
- NMA Project – this action allows you to change the NMA status of the Project. By default, this is set to "Project is not NMA". If unsure, the HREC Office can advise and adjust this setting.
- Print – This will generate a pdf of the form, which can be printed or saved.
- Correspond – you will be able to send a Notification to the Administrators within ERM, once the form is submitted.
- Import XML – this action is only available on the HREA. It allows you to import the XML version of a HREA created in hrea.gov.au.

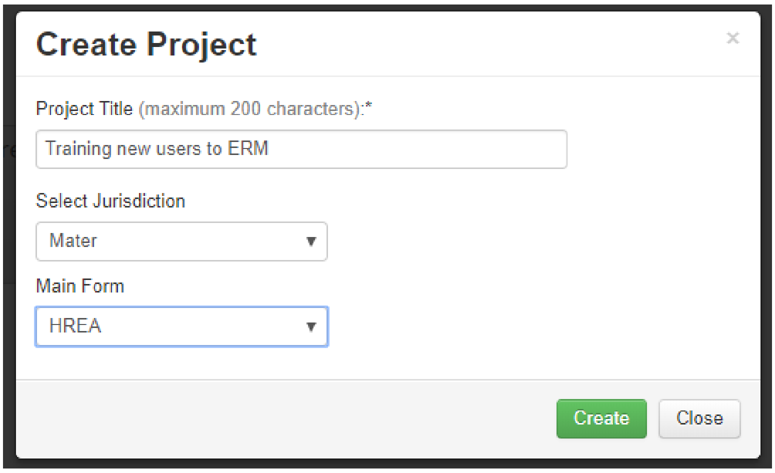
Search for an existing Project

To search for existing Projects, use the Search Projects field above the list of Projects.

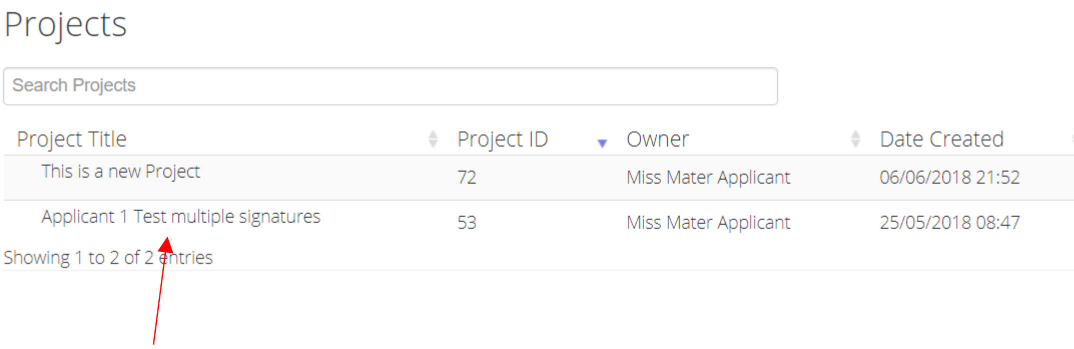
- Your Project may be in ERM, but you may not be able to see it if you were not the Applicant or if the Project Owner has not yet shared required forms with you in ERM.
- Consult with your study personnel to see if they have access to the Project in ERM. If so, then request that they share relevant forms with you, 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 number. They can search for your Project. If it is in ERM, they will advise you to contact the Infonetica Help Desk who can assist with gaining access to the Project.

Create a new Project

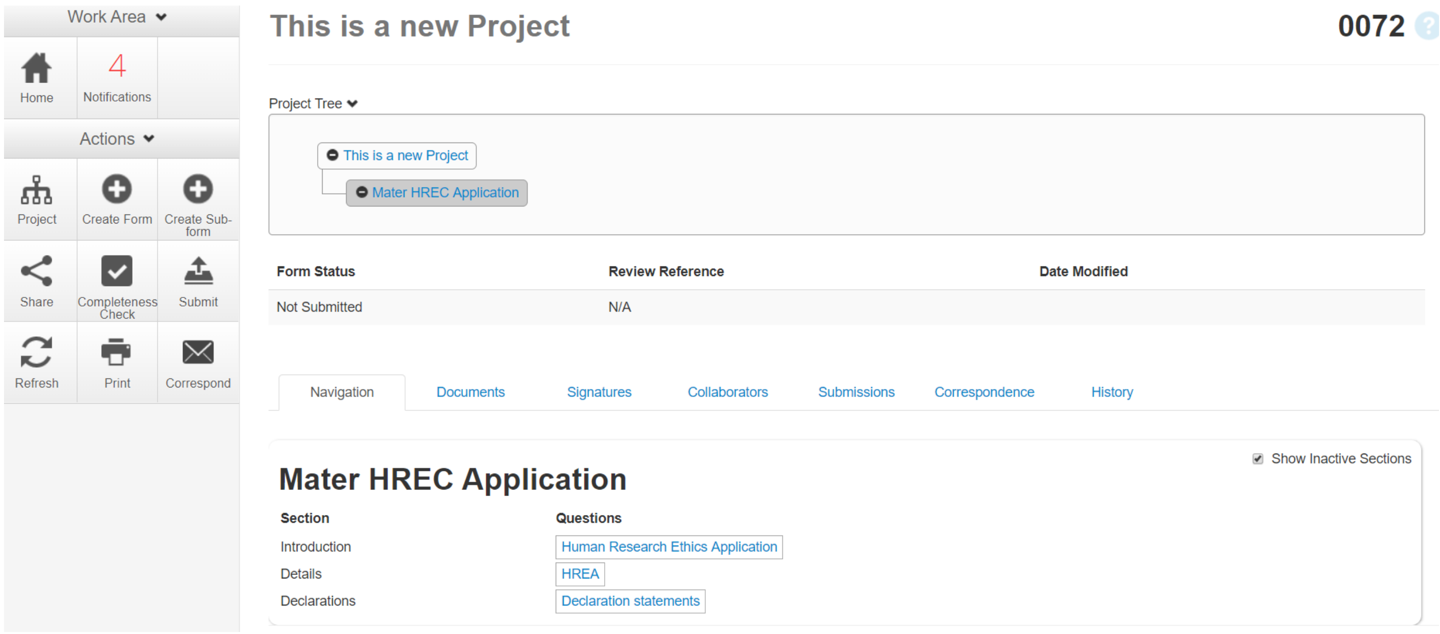
- Click on the Create Project action tile.



- This will prompt you to enter a Project Title. **This is the Short Title of your project. Ensure it is correct as it cannot be changed easily once it is entered.**
- Select Mater Misericordiae Ltd as your Jurisdiction
- Select your Main Form from the list. (Refer to Appendix A for guidance on the Main Forms.)
- 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 and view the Main Form and available Actions.



The Project Tree displays all forms created in this project that you have been given access to. If all forms in the Project have been shared with you, then you will be able to see all the forms in the Project Tree.

Form Status is the current status of the form. It will change as it moves through the Submission and Review phases.

Review Reference will be allocated when you submit the form. It will be similar in format to the current HREC number e.g. HREC/MML/99999 (V1) where HREC is the form ID, MML is the reviewing HREC, 99999 is the Project ID and V1 represents the version of the submission.

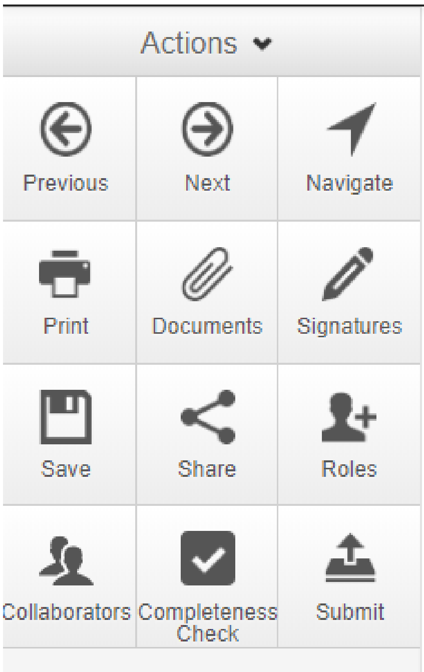
The row of tabs shows a range of information that will compile as the form moves through the Submission and Review phases:

- 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, Contacts listed in the form and people with whom the form has been shared. You can adjust their Form access permissions from here.
- 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

The form itself shows sections in blue that contain questions for completion. Click on the blue Questions to navigate directly to that section in the form, instead of paging through the form.

Complete a Form and Submit

- Click on a blue Question to access the form. These are the Actions you can then perform:



- Use the Previous and Next action tiles to navigate between the sections within the form. Changes will be saved as you move to a different page.
- Navigate button – takes you from within the form back to the Project Tree where you can access the sections of the Form. All changes will be saved
- Print – this generates a pdf of the form, which can then be printed or saved
- Documents – this allows you to view all documents uploaded into the form
- Signatures – this tile 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 once it becomes 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 – shares the form with others who need to see your form. This gives them access and you can set their permissions.
- Roles – shares the main form and/or sub-forms with others using pre-defined sets of permissions
- Collaborators – these are the other personnel listed on the form in the Contact questions and personnel you have shared the form with
- Completeness Check – shows mandatory questions not completed. Use this before signing or requesting electronic signatures
- Submit – allows you to submit your form. This does an automatic Completeness Check
- Unlock – use this action to Unlock the form if fields need to be updated after the form has been locked

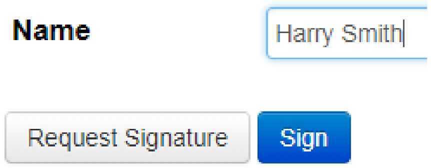
Electronic Signatures

Signatures on all Mater ERM forms (except the HREA) 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 <u>all</u> 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.

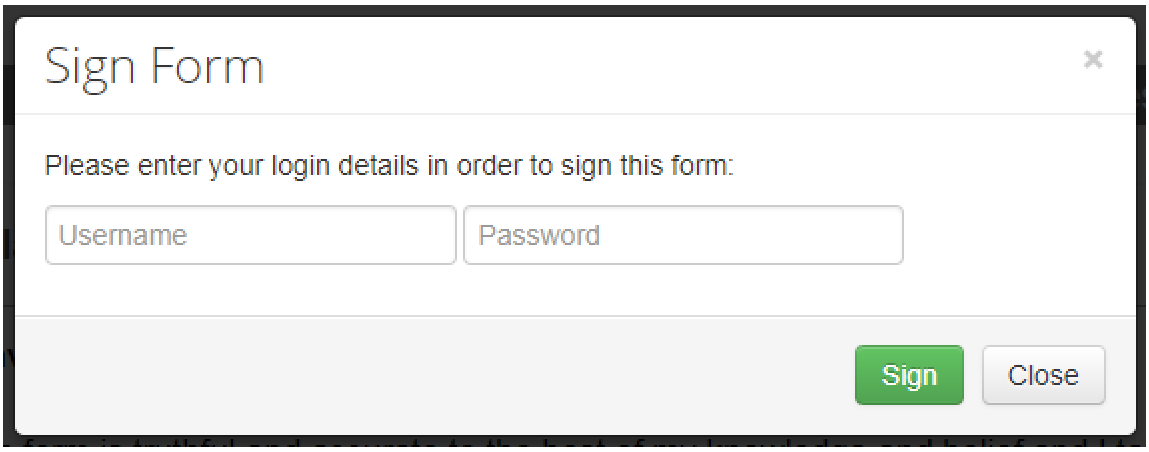
To send a request for an electronic signature:

- 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 request them to create their account. When they have an ERM account, you can then request a signature from them.



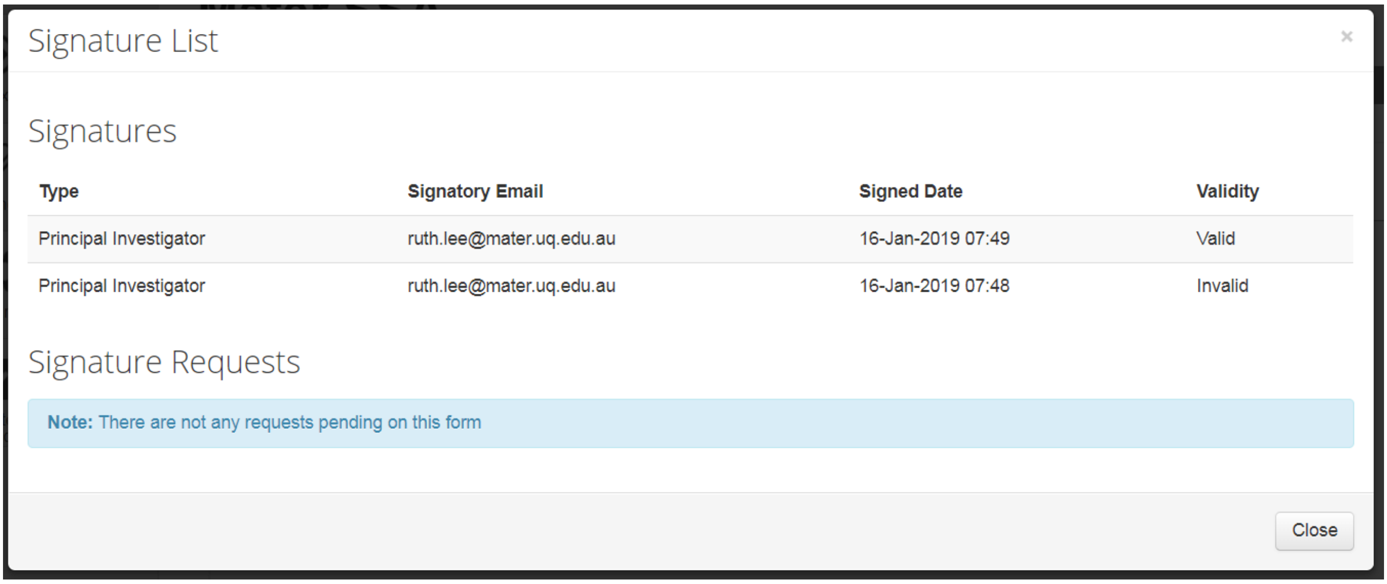
To sign electronically:

- Click on the Sign button (if you have accessed the form from the Projects list) or the Sign action tile (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.

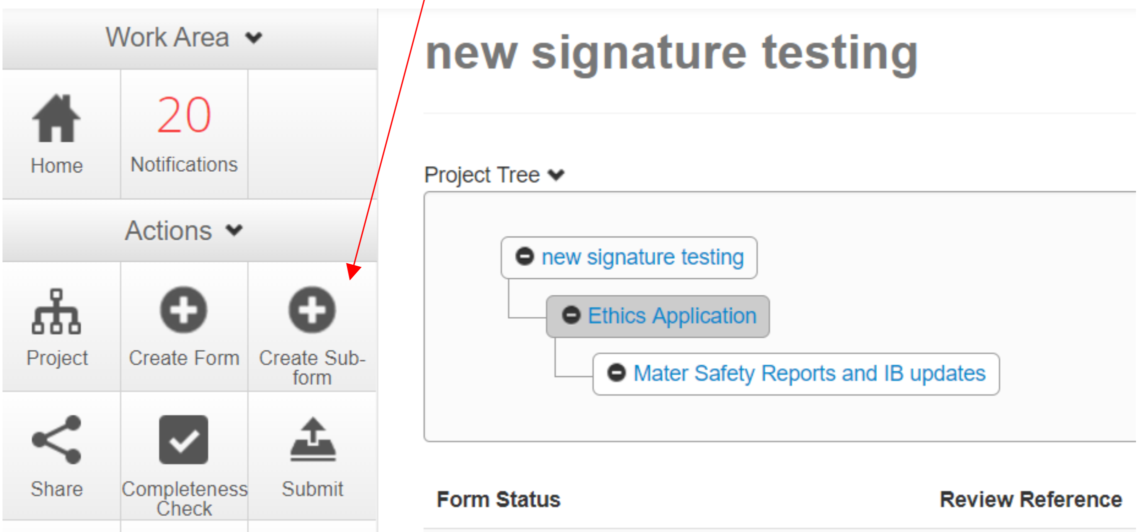
Click on the Signatures action tile within the form for a list of signatures collected, signatures requested and their associated statuses:



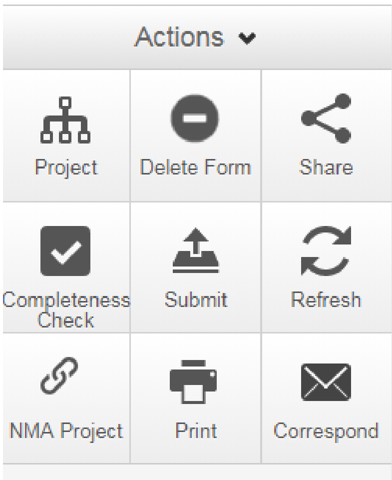
The Signatures tile in the General section of your Work Area provides a list of Signature Requests sent to you and their associated status.

Create Sub-form

- The Mater Site-Specific Assessment form, Mater Amendment form, Mater Progress and Final Reports, Mater Serious Adverse Event Initial Form, Mater Safety Reports and IB Updates Form are all sub-forms of the HREA.
- To create these sub-forms, ensure the HREA is highlighted then click on Create Sub-form Action button. The dropdown menu will display your choices.



- On a sub-form, you have the option to Delete Form, prior to submitting it:



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

Sharing forms

You can share **forms** in ERM to provide collaborators and other study personnel with access for the purposes of reviewing, signing, updating, creating and submitting forms. Their level of access is defined by you.
You can share forms created in the **Mater jurisdiction** by using either the Roles action or the Share action.

Roles Action

The **Roles** action enables you to share the main form only **or** share all sub-forms with basic access to read the main form **or** share all forms within a Project with nominated personnel, 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
- Click on the **Main Form** (the first form under the Project title in the Project Tree. This can be a HREA, an MDF, a DM HREC MDF for example. HREA's that have been migrated into ERM are called 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 B 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 Collaborators tab to Edit Permissions.

To provide access to **all Mater sub-forms in the project** (i.e. all Mater forms that are created after the Main form):

- Click on the Project
- Click on **any Mater sub-form** 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 Sub-form access to the Main form as well.

To provide access to the **Main form and all Mater sub-forms 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.

To change permissions applied by a Role, the role must be removed, and a new role applied, or Share could be used instead.

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 sub-form), 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.

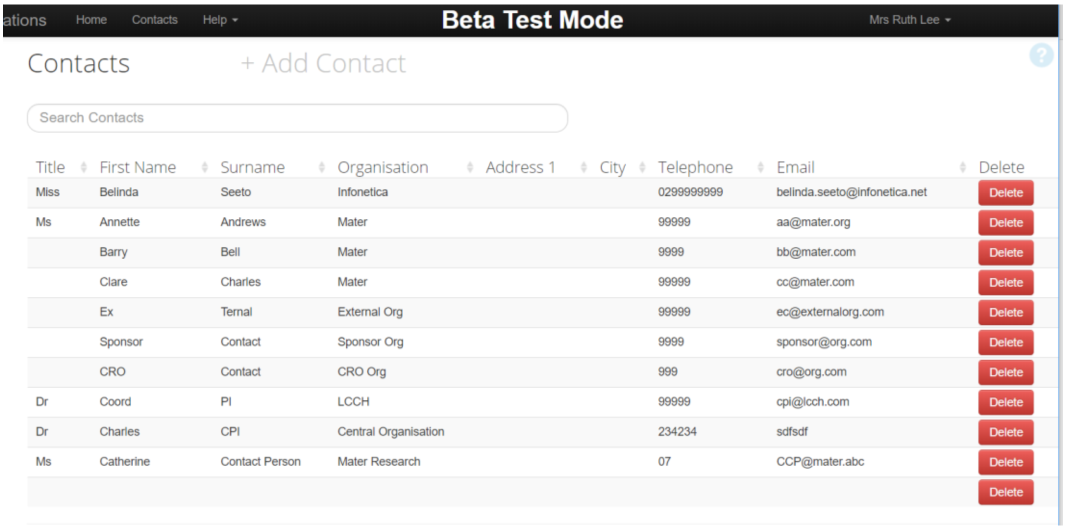
If you need to modify permissions given to a study team member, use the Collaborators tab to Edit Permissions.

Forms returned for Further Information

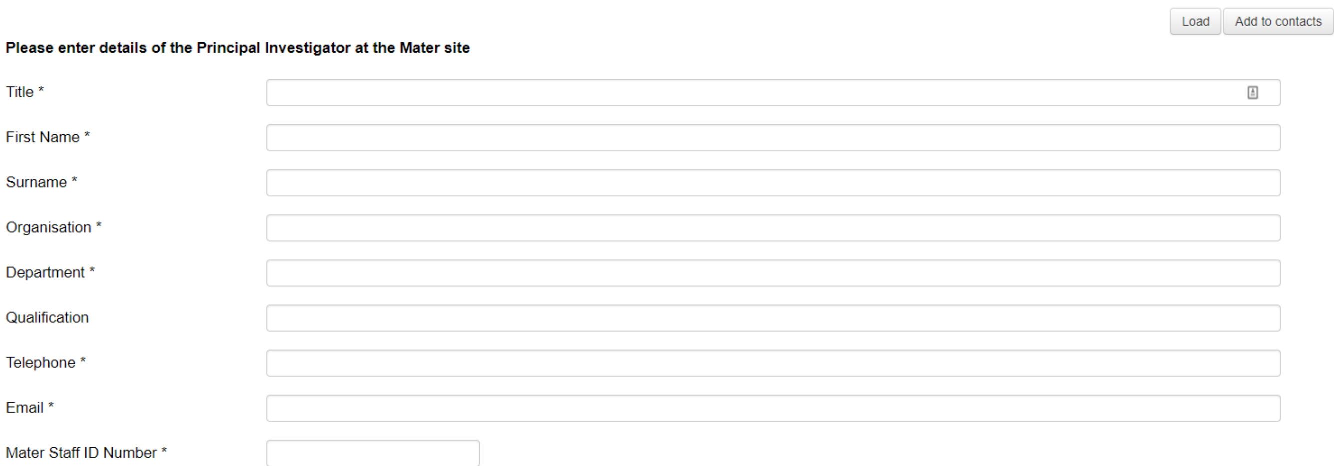
- If the HREC, RGO or EPCT EAC Administration Offices request further information from you, they may unlock the form so you can update it. This will invalidate electronic signatures, but you may not need to re-collect all signatures, depending on the requirements of the HREC or RGO.
- You will receive a Notification in ERM and an email containing details of the request.
- When you have provided further information, such as changing information in form fields or uploading a new or replacement document, collect the required electronic signatures then click Submit to send it back to the Administrators for continued reviewing.

Contacts

- You can keep your personal list of Contacts in ERM.
- Click on the Contacts menu item in the top bar to add and update your Contacts.
- The most useful method of adding Contacts to your list is from within the forms on the Contacts questions.

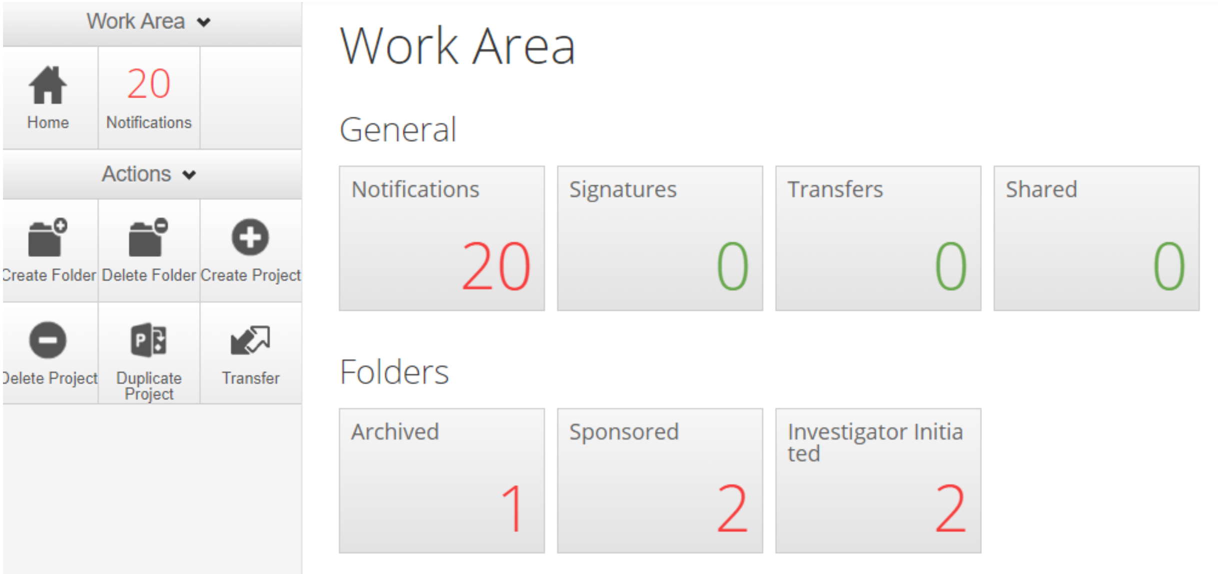


- When entering Contact details in forms, after entering their details for the first time, you can “Add to Contacts” and this will save their details in your Contact list. The next time you need to enter their details, you can “Load” their details from your Contact list instead of entering them again.
- 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.
- You can also rename and delete folders.

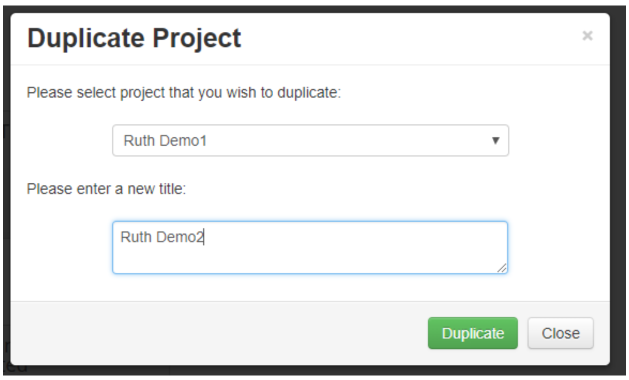


Delete Forms and Projects

- You can delete sub-forms - 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. Sub-forms must be deleted first then the Project can be deleted. This also deletes the main form.

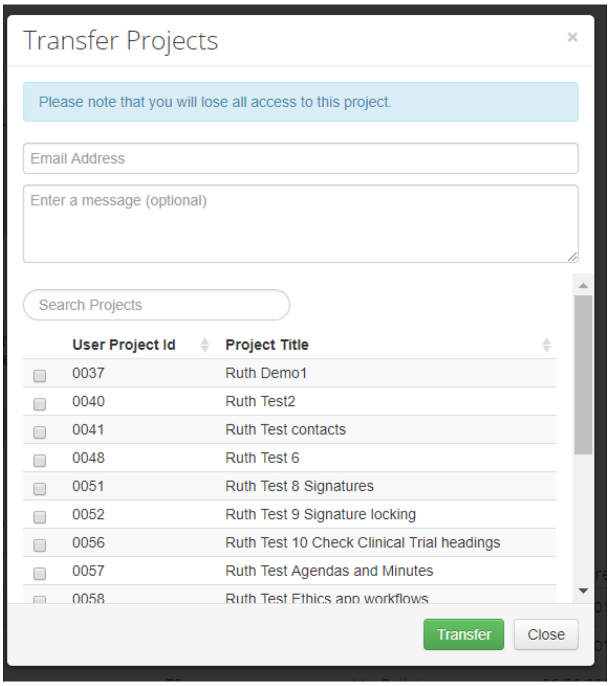
Duplicate Project

- You can duplicate a Project.
- This will create a new project containing the same forms as the project that you selected to duplicate.
- The forms will contain the information entered on the original forms but documents from the original forms are not included.



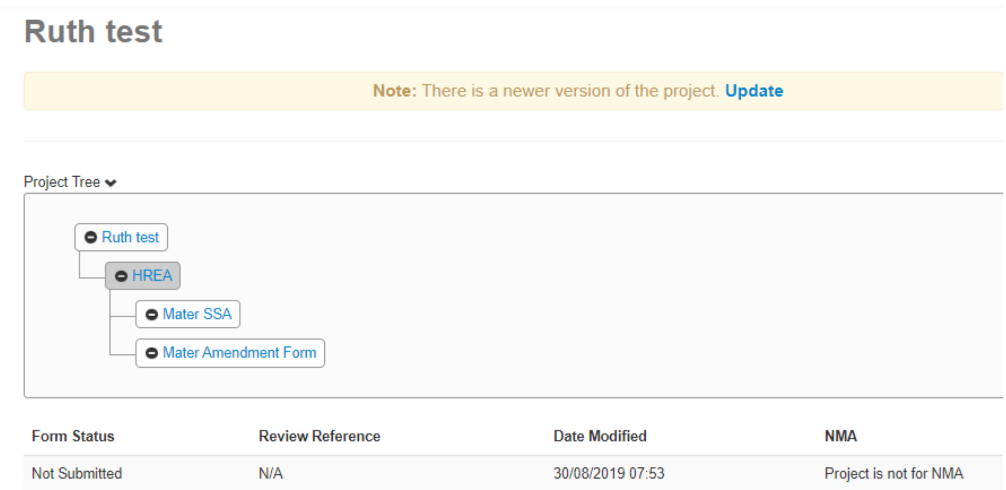
Transfer Projects

If you are the Project Owner (the person who created the Project) you can transfer 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.



Update Projects to access latest version of forms

If you are the Project Owner (the person who created the Project) you will need to update projects following re-publishing of forms by the Administrators, 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.

Before updating a project:

- Always check for unsubmitted forms in the project
- Open unsubmitted forms to check if they are locked
- If a form is locked, then delay updating the project until it has been submitted if possible
- If a 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.

If the project is OK for updating, then click the blue Update button in the above message. The update may take several minutes to complete.

Appendix A – Main Forms

- HREA – select this form for all Human Research Ethics applications which are not a Quality Assurance Activity or a research activity exempt from HREC review.
- Mater Quality Assurance and Exempt Research Form – select this form for Quality Assurance applications (i.e. not research) and for Exempt Research applications.
- MDF – select this form when your study has been reviewed by a HREC that does not use ERM and you are submitting an SSA to the Mater Research Governance Office.
- Mater Authorised Prescriber – select this form to request Authorised Prescriber endorsement from the MML HREC.
- EPCT Risk Assessment – select this form to submit an Early Phase Clinical Trials Risk Assessment to the Early Phase Clinical Trials Expert Advisory Committee (EPCT EAC).

Appendix B – 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, provides the collaborator with ability to create subforms
  - **Main Forms** (read/write/subforms/share) – in addition to reading and creating subforms, provides the collaborator with the ability 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 to read the main form and all subforms only
  - **Full Project** (read/subforms) – in addition to reading all forms, provides the collaborator with ability to create subforms and receive notifications
  - **Full Project** (read/write/subforms/share) – in addition to the above, provides the collaborator with the ability 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 Sub-forms:
  - **Subforms** (read only) – allows collaborator to read all sub-forms and read the main form
  - **Subforms** (read/write/subforms) – in addition to reading, provides the collaborator with ability to update all sub-forms, read the main form, create sub-forms from the main form and receive notification
  - **Subforms** (read/write/subforms/share) – in addition to the above, provides the collaborator with the ability to share all sub-forms
  - **Subforms** (read/write/subforms/share/submit) – in addition to the above, allows the collaborator to submit all sub-forms

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