Ethics Review Manager (ERM)

Frequently Asked Questions for Mater Users

mater research

Contents

ERM User Guide for Mater Researchers

- This FAQ document provides answers to frequently asked questions.
- For a full guide on how to use ERM and its capabilities, refer to the ERM User Guide for Researchers, available from the Ethics and Governance page on the Mater Research website.

How do I login to 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.

FAQ's within ERM

Once logged into ERM, click on **Help** in the top menu bar. This contains detailed information about common processes within ERM and specific help for each ERM jurisdiction (Mater (Qld), Queensland Health and Department of Health Victoria).

Is my project already in ERM?

All projects submitted to Mater (Qld), Queensland Health and Department of Health Victoria via the Online Forms platform prior to 9 July 2018 have been migrated into ERM.

My project should be in ERM, but I can't find it.

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 given you access to the project within ERM.

- Ask your study team if they have access to the project in ERM. If so, request that they give you a **Role** in the project, that enables you to create subforms and submit. This will give you the access to view the project and perform these actions. (Refer to the 'How do I share a project in ERM' section.)
- 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 the Project Title and HREC approval reference. They can search for the project. If it is in ERM, they can tell you who can give you access to the project.

How do I give team members access to a project in ERM?

You can give access to **forms** 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.
You can give access to forms created in the **Mater jurisdiction** by using either the Roles action or the Share action.

Roles Action

The **Roles** action can provide access to the main form **or** all sub-forms and the main form within a project, in a single 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.
- 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 Sub-form 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.

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.

Hot Tip: *Give your study team members access to your project as soon as possible following the creation of your project in ERM. The* ***Roles*** *action is the fastest method.*

How do I submit a HREC application to Mater HREC?

All Human Research Ethics Applications to the MML HREC must be submitted via ERM.

Before beginning, ensure that your project has not already been created in ERM.

- Login to ERM
- Create a new project – enter the title of your project. Ensure it is correct!
- Select Mater Misericordiae Ltd as the **Jurisdiction**
- Select HREA as the **Main form**
- Complete the HREA, uploading all required documents, sign then submit.

How do I load my completed HREA into ERM to submit to Mater HREC?

If you have already completed your HREA (in hrea.gov.au), you can import the XML version of the HREA into ERM. You do not need to recreate it.

Before beginning, ensure that your Project has not already been created in ERM.

- Login to ERM
- Create a new project – enter the title of your Project. Ensure it is correct!
- Select Mater Misericordiae Ltd as your **Jurisdiction**
- Select HREA as the **Main form**
- In the Introduction section of the HREA, instructions will guide you on how to import the XML version of your HREA into the ERM HREA (using the XML Import action tile).
- Complete any outstanding information in the HREA and submit.

How do I submit an SSA to Mater Research Governance Office?

The Mater SSA form is created as a subform of the main forms (e.g. HREA, MDF).

- Login to ERM
- Find your project
- Click on the main form in the Project Tree (HREA, MDF, DM HREC or QA and Exempt)
- Click the **Create Subform** action
- Select Mater Misericordiae Ltd as the **Jurisdiction**
- Select Mater SSA
- Click **Create**
- Complete the SSA form and submit.

The Lead HREC will not approve my project for the Mater site. I need to submit my Ethics Application to Mater HREC for review.

This scenario may occur when Mater is being added as a site to a study and the lead HREC will not approve for the Mater site.

To cater for this scenario, you will need to create a new project in ERM so that you can generate a HREA to submit to the Mater HREC.

- Login to ERM
- Create a new project – enter the title of your project. (Suggestion: Make it similar to the existing project title but include a reference to Mater.)
- Select Mater Misericordiae Ltd as the **Jurisdiction**
- Select HREA as the **Main form** then click **Create**

- If you have an XML version of your completed HREA, then follow the instructions in the form to upload the XML version using the XML Import action tile.
- Complete any outstanding information in the HREA and submit
- If you don't have an XML version, then you will need to complete all required fields manually. (Note: you can use copy and paste.)
- Complete the HREA and submit.

How do I submit an amendment or report to Mater HREC?

All amendments and study report submissions to the MML HREC must be submitted via ERM. If you are submitting to the Mater RGO as well, then only one submission is required. You must select this option at the beginning of the form. Your submission will then be directed to both the MML HREC and the Mater RGO.

- Login to ERM
- Find your project
- Click on the HREA
- Click the **Create Subform** action
- Select Mater Misericordiae Ltd as the **Jurisdiction**
- Select the appropriate subform of the HREA
- On the form, select the option to submit to either MML HREC only or both MML HREC and Mater RGO.
- Complete your form and submit.

How do I submit an amendment or report to Mater Research Governance Office?

If your project was approved by the MML HREC:

- Refer to the "How do I submit an amendment or report to the Mater HREC? FAQ above.
- On the form, select the option to submit to "Both MML HREC and Mater RGO".

If your project was approved by a HREC other than MML HREC but within Queensland Health or Department of Health Victoria:
Your project should exist in ERM.

- Login to ERM
- Click on your project
- Click on the HREA
- Click the **Create Subform** action
- Select Mater Misericordiae Ltd as the **Jurisdiction**
- Select the appropriate subform of the HREA, and click **Create**
- On the form, select the option to submit to "Mater RGO only"
- Complete your form and submit.

If you cannot see your project in ERM, refer to the "My Project should be in ERM but I can't find it" FAQ.

If your project was approved by an external HREC, not Queensland Health and not Department of Health Victoria:
Your project may or may not be in ERM, depending on where your approving HREC is located.

- Login to ERM

- If you cannot find your project, refer to the "My project should be in ERM but I can't find it" FAQ.
- If your project is in ERM,
    - Click on your project
    - Click on the Main form (most likely MDF)
    - Click the **Create Subform** action
    - Select Mater Misericordiae Ltd as the **Jurisdiction**
    - Create the appropriate subform
    - Select the option to submit to "Mater RGO only"
    - Complete your form and submit
- If your project is not in ERM, contact the Mater Research Governance for assistance with creating your project and creating an MDF. Once this is done, you can then create an amendment or report as a subform of the MDF.

How do I add an electronic signature to an ERM form?

All signatures on Mater ERM forms are required in electronic format.

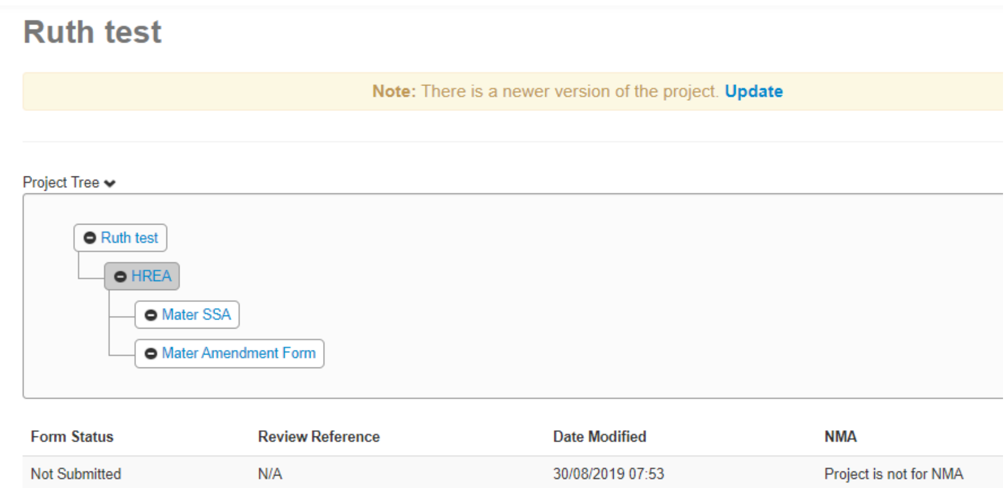
If you are required to sign an ERM form, you may either:

- Navigate directly to the signature question in the form and click the blue **Sign** button (if you are the Principal Investigator or the Mater Contact); or
- Receive a request for your signature via email. The email contains instructions on how to login to ERM, navigate to the form to review its contents and click on the **Sign** or **Reject** action.

Electronic signature training guides, targeted at a range of different roles, are available via the Ethics and Governance page on the Mater Research website.

Why do I need to update my project?

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 ERM 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.

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