Ethics Review Manager (ERM)

Frequently Asked Questions for Mater Users

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 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
- Click on Login from the dropdown menu on the top right.
- Login using your Online Forms email address and password. If you cannot 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.

If you are not sure if an ERM account has been created for you, contact the Infonetica Help Desk.
If advised to create your account:
- Go to au.forms.ethicalreviewmanager.com
- Click on New User
- Enter your details ensuring the email address is correct. This will be your ERM username and the contact email address used by ERM for correspondence and communications. An email will be sent to you supplying instructions on how to activate your 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 Health Victoria).

Is my Project already in ERM?

All projects submitted to Mater (QLD), Queensland Health and Health Victoria through Online Forms 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 Applicant or if the Project Owner has not shared the project with you in ERM.
- Consult with your study personnel to find out if they have access to the Project in ERM. If so, then request that they share the Main Form (most likely the HREA) with you, using the **Roles** action that enables you to create sub-forms and submit. This will give you the access to view the Project and perform these actions.
- 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 the Project. If it is in ERM, they will advise you to contact the Infonetica Help Desk who can assist you with gaining access to the Project.

How do I share a Project in ERM with other study personnel?

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.
- 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 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:
Share forms with your study team members using the Roles action in all your Projects as soon as possible following the creation of your Project in ERM.

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 Short Title of your Project. Ensure it is correct!
- Select Mater Misericordiae Ltd as your jurisdiction

- Select HREA as the Main Form
- Complete the HREA, uploading all required documents and 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 Short 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 sub-form of the main forms, which are the Ethics application forms.

- Login to ERM
- Find your Project
- Click on the Main form in the Project Tree (HREA, MDF, DM HREC or QA and Exempt)
- Click on the "Create Sub-Form" Action tile
- Select Mater Misericordiae Ltd as your jurisdiction
- Select Mater SSA
- Click Create
- Complete the SSA form and submit

When your SSA application has been authorised by the Mater Research Governance Office, your Project will then be created automatically in the Mater Research Hub. It will be populated with information that you provided in your SSA application.

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 Short Title of your Project. (Suggestion: Make it similar to the existing Project title, but include a reference to Mater.)
- Select Mater Misericordiae Ltd as your jurisdiction
- Select HREA as the Main Form

- 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 your HREA and submit

Where are my previously submitted Amendments and Reports in ERM?

Migration of post-approval data from the AU RED system to ERM was performed from 10 – 12 August 2018 with associated documents migrated from 17 – 20 August 2018.

If you are the project or form owner of a project in ERM or have been given access to a project, you may notice new forms in your project tree.

- DM HREC Amendment. This is a migration form containing data that has been copied from the AU RED system relating to amendments that have been submitted to the HREC Office. All amendment processing was finalised in AU RED prior to migration, so these migration Amendment forms in ERM require no further action.
- DM HREC PAF (Data Migration HREC Post approval form). This is a migration form containing data that has been copied from the AU RED system relating to the study status and any reports provided and tracked by the MML HREC Office. This is a READ ONLY form. This form cannot be modified or re-submitted. No further action is required for these specific forms.

For all future submissions of Amendments and reports to the HREC Office, appropriate sub-forms must be completed and submitted via ERM. Instructions are available in User Guides on the Mater Research website.

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 on the "Create Sub-Form" Action tile
- Select Mater Misericordiae Ltd as your jurisdiction
- Select the appropriate sub-form 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 Health Victoria:
Your Project should exist in ERM.

- Login to ERM
- Click on your Project
- Click on the HREA
- Click on the "Create Sub-Form" Action tile
- Select Mater Misericordiae Ltd as your jurisdiction
- Select the appropriate sub-form of the HREA
- 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 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)
  - Select Mater Misericordiae Ltd as your jurisdiction
  - Create the appropriate sub-form of the HREA
  - 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 a report as a sub-form 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 (except on the HREA).

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 actions.

Training Guides, targeted at a range of different roles, are available via the Ethics and Governance page on the Mater Research website.
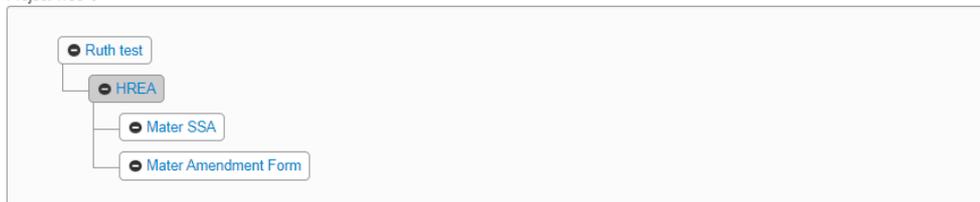
Why do I need to update my project?

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 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 above message. The update may take several minutes to complete.