Ethics Review Manager (ERM) User Guide for Researchers

Queensland Government

Contents

Introduction

Ethics Research Manager (ERM) is the latest feature-rich version of Infonetica's well established ethics management software previously known as RED (Research Database) and Online Forms.

Queensland Health, Victorian Health Services and Mater Misericordiae Ltd commenced using ERM and AU FORMS in July 2018 for all research projects involving humans. Information about submitting an application for all research projects involving humans on the new forms can be found on your local Hospital and Health Service (HHS) website.

Login to ERM

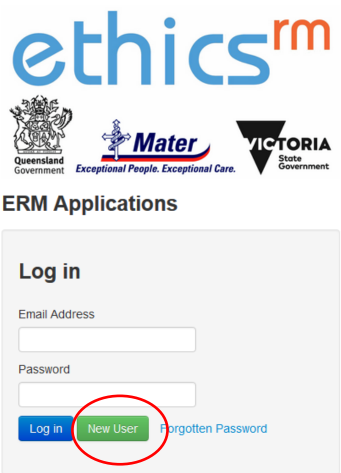
If you have used Online Forms previously to create and submit an HREA you have an ERM account.

Login using your Online Forms email address and password. If you can't remember your password, click on **Forgotten Password** link on the login page. If you have trouble logging in, email the Infonetica Help Desk.

Online Forms remains available to review and copy previous applications. Currently Online Forms remains in use in NSW Health, SA Health and the ACT.

Create a new account in ERM

If you are a first-time user in ERM and have not previously used Online Forms click on **New User** and follow the prompts to create an account.

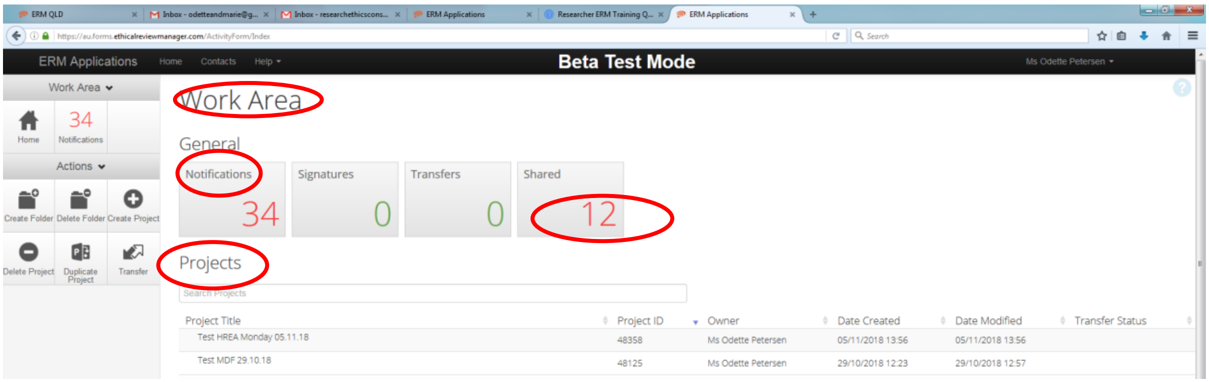


If you are not a first-time user and you create a new account you will have two accounts and will not be able to access previous research with this new account. If you have trouble logging in, email the Infonetica Help Desk.

Work Area

The tiles in the **General** work area (see screen shot below) will open when you click on them. The numbers appear in red when they contain items that have yet to be read or actioned.

Projects created are listed under the **Projects** header in the general working area.

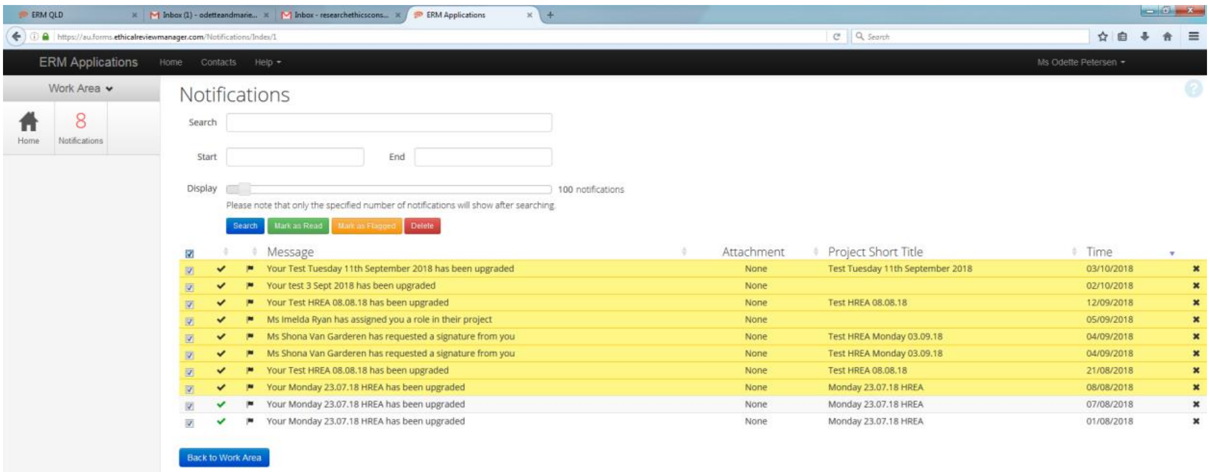


If you have unread notifications the number will appear in red font. It is like your email inbox.

- 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 from you.
- The **Shared** tile will show the Forms that have been shared with you.

Notifications

- Click on **Notifications** to read your messages. ☑ the message you want to action.

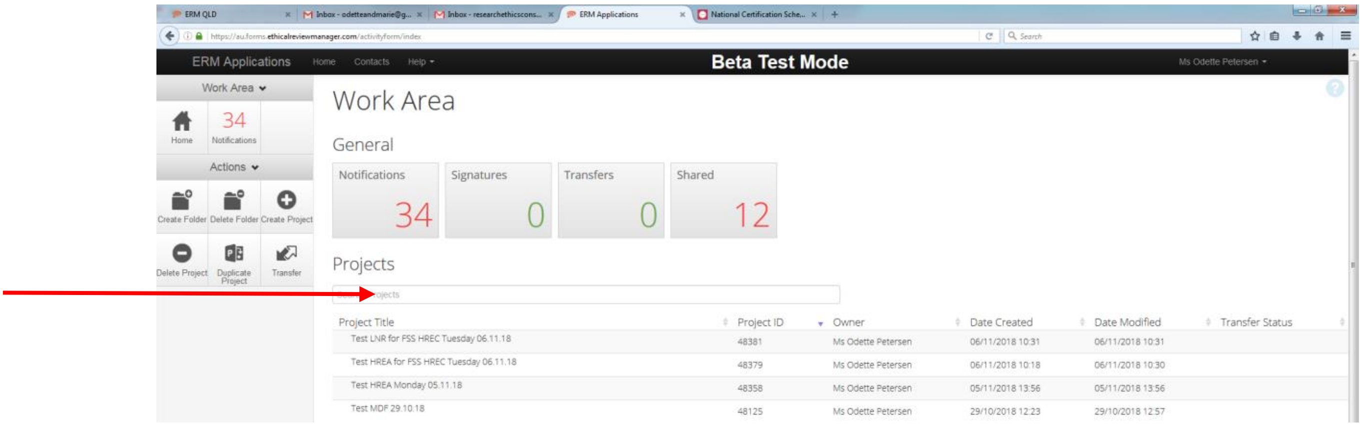


- You can mark **notifications** as unread, read, flag them or delete them. If you wish to mark some unread, and delete others, you will need to ☑ and action unread and then ☑ and action delete.

- Always check **Notifications** when you login as you may receive notifications from the HREC or RGO Administrators.

Search for an existing Project

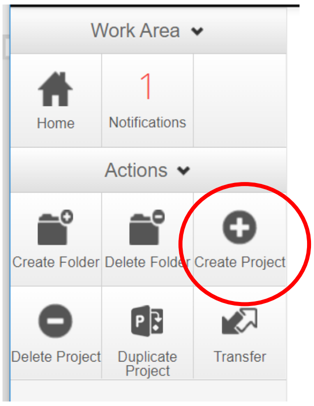
To search for existing projects, use the **search projects** field under the **Projects** header in the general work area. This search is restricted to projects listed on the Work Area. If you have created folders and moved projects to folders, you will need to perform separate searches in each of the individual folders.



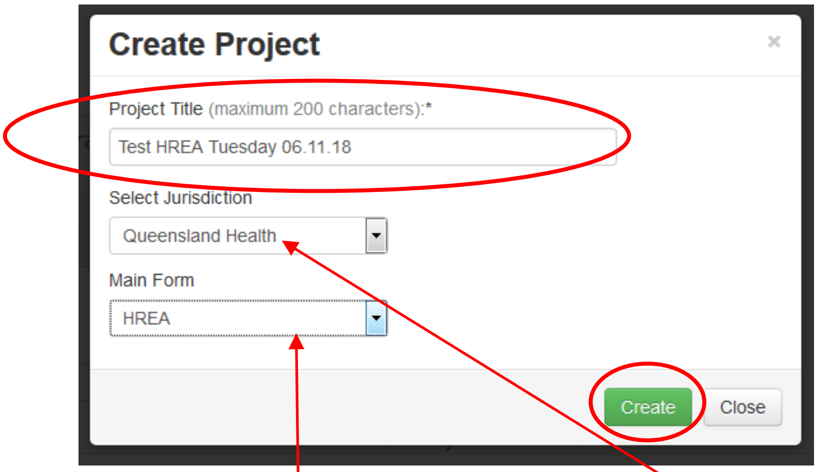
- Your Project may be in ERM but you may not be able to see it if you were not the Applicant or if the Project Owner has not yet shared the project with you in ERM.
- Consult with your study personnel to find out if they have access to the Project in ERM. If so, then request that they share the main form (HREA, LNR) with you, using “Roles” action. This will give you access to view the form and attached documents and allow you to create sub-forms such as your local SSA.
- If no one in your study team has access to the Project, contact your local HREC or RG office and provide the title and HREC number. They can search for your Project. If it is in ERM contact the Project owner and ask for your role to be created against the Project. If you don’t know who the Project owner is contact HIIRO REG for further advice.

Create a new Project

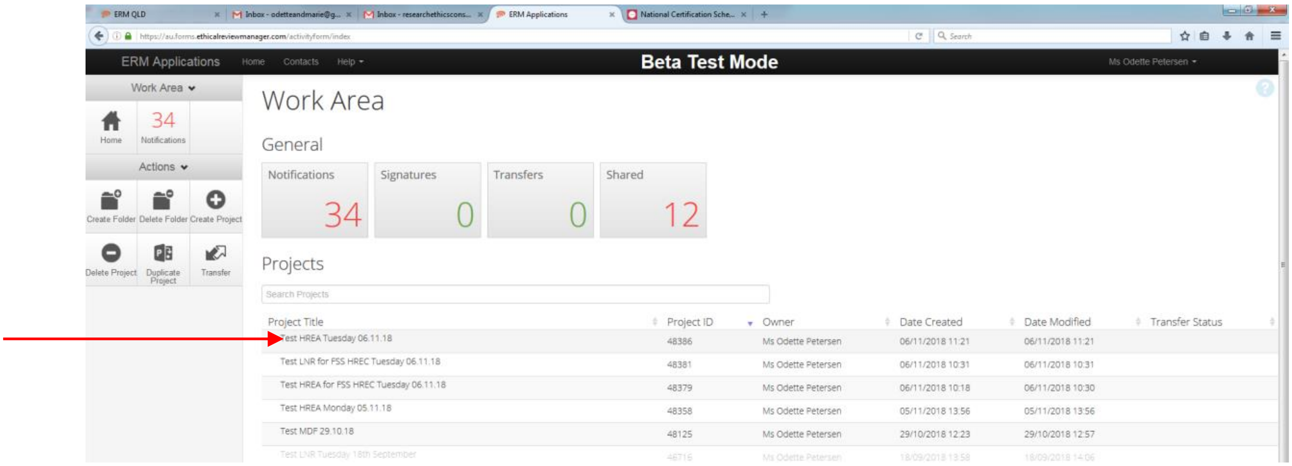
Click **Create Project** action button on the left of your screen.



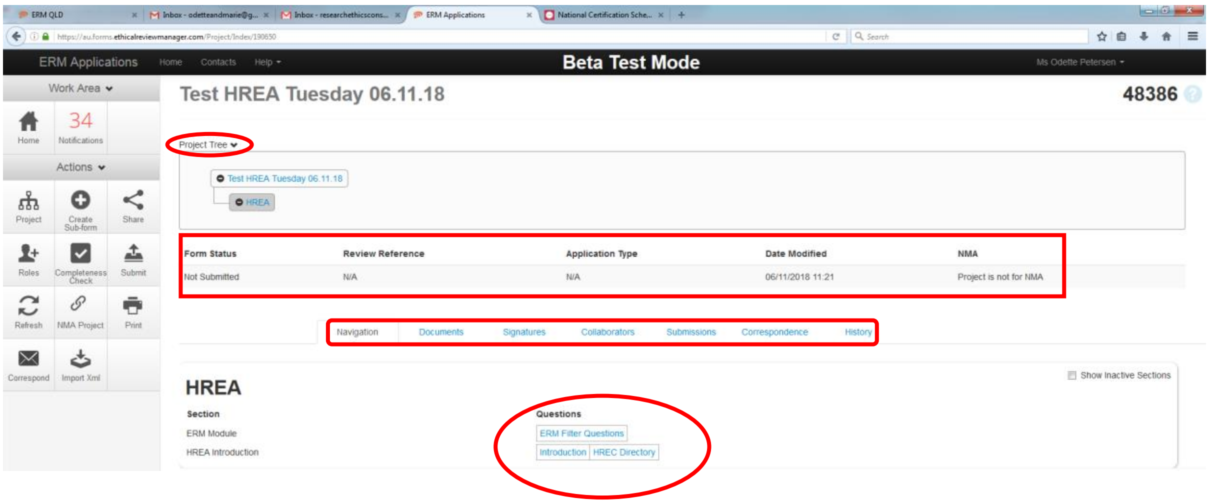
- This will prompt you to enter a **Project Title**. **This is the short title of your project. Ensure it is correct as it cannot be changed once it has been entered.**



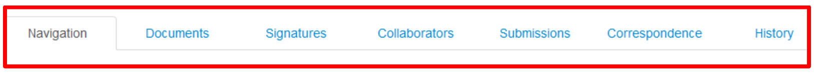
- Select **Queensland Health** as your **Jurisdiction**.
- Select your Main Form from the list e.g. HREA, LNR.
- Click **Create** to create your Project. A Project ID will be allocated and the main form – HREA or LNR will be created and available for you to complete.



- Click on the **Project** you have just created to complete your application.



- The **Project Tree** *above* will display all forms created in this project that you have access to.
    - **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.
- **Row of tabs**:



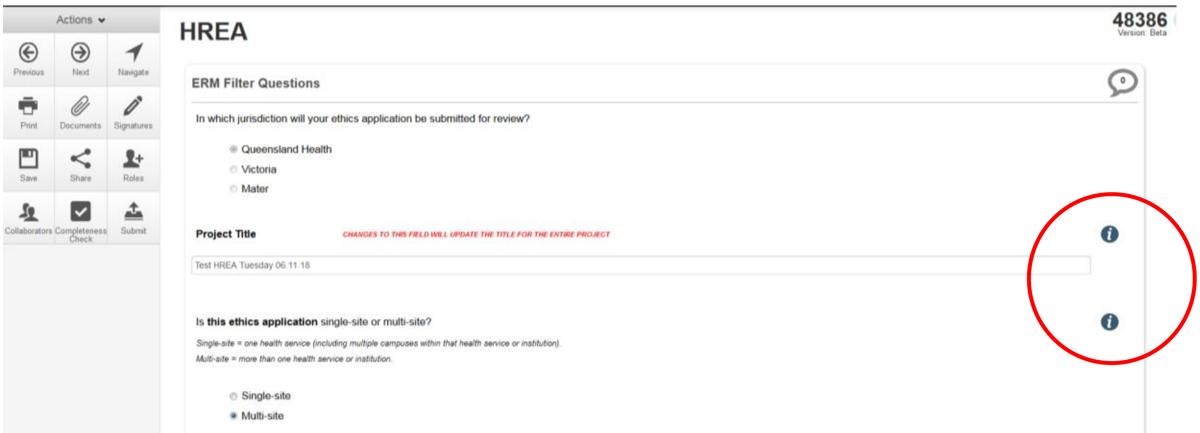
    - **Navigation** allows you to navigate directly to a section of the form
    - **Documents** displays documents uploaded in the form
    - **Signatures** displays electronic signatures entered on the form and signature requests that have been sent

- Collaborators displays the project owner, form owner, contacts listed in the forms 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).
- **Correspondence** displays ERM internal correspondence related to the form
- **History** displays all events occurring in the form

- The Form itself shows sections in blue that contain questions for completion.

- Commence by completing the ERM filter questions. This information is very important for your reviewing HREC. It asks questions that are not in the HREA such as participating sites that are listed in the HREC approval letter.

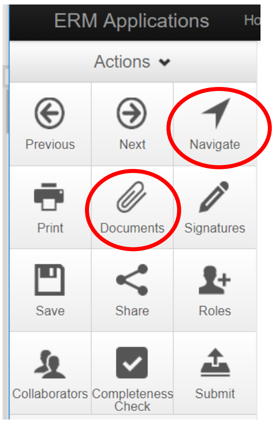
- **Information Icons** are inserted throughout the forms (right hand side, blue circle with"*i*" inside), to provide guidance. Click on the icon to see the text.



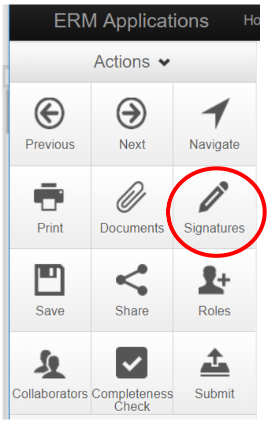
Adding Documents to the application

- Documents upload prompts are placed at relevant questions throughout all applications. Follow the prompts to upload documents as you go. You can review uploaded documents at any time by clicking the **Documents** button *seen in the screen shot on the following page*.

Actions



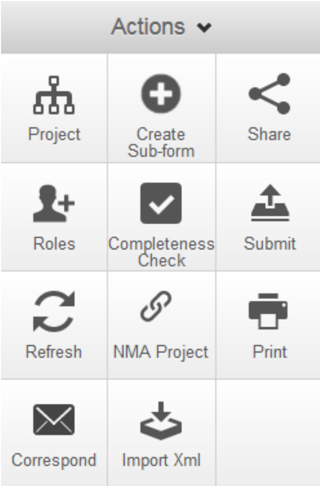
- Click **Next** or **Previous** in your **Action** buttons to move to the next or previous page in the application form.
- Click **Navigate** to return to the beginning of this application followed by **Home** *(next screen shot)* to return to your **Work Area**.



- **Signatures** can be collected either by uploading declaration emails or entering electronic signatures. When an electronic signature is requested, all fields on the form are locked (except other signature requests) so you cannot enter any further information. Ensure all fields are completed before requesting any electronic signatures. You can “Unlock” the form but this will rescind all signatures and signature requests previously requested.

  If you are submitting an LNR application for exemption, electronic signature is the only option available.

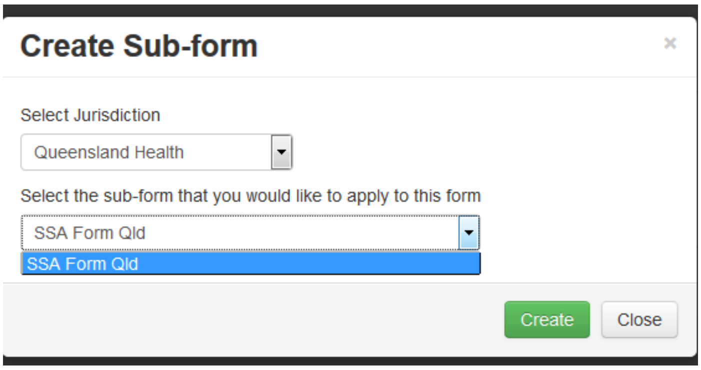
- **Save** saves the latest changes to the form. Clicking “next” or “previous” also saves your work on the current page.



- **Project** will take you to the Project level and display the Project Tree
- **Create Sub-Form** creates a sub-form of the current form e.g. sub-forms for the HREC application (HREA or LNR) include SSA, Amendments, Progress and Safety Reports.
- **Share** – it is recommended this action is <u>not used</u>.
- **Roles** – <u>it is recommended this action **is used**</u>. This allows you to share this form with other study personnel. Permissions are pre-defined.
- **Completeness check** will check that all mandatory questions in the form have been answered before you submit.
- **Submit** will submit the form. However, if mandatory questions have not been answered it will now allow you to submit.
- **NMA Project** allows you to change the status of the project. By default, the project is set to “project is not NMA”. If the study will be reviewed under single ethical review for multi-centre research and participating sites include public hospitals in Qld, NSW, ACT, Vic, SA, and WA, it is an NMA project.
- **Print** will generate a pdf of the form which can then be printed or saved.
- **Correspond** allows you to communicate with your HREC office if you have any questions prior to submitting the form or at any time throughout the life of the project.
- **Import XML** allows you to import an HREA that has been created in hrea.gov.au.

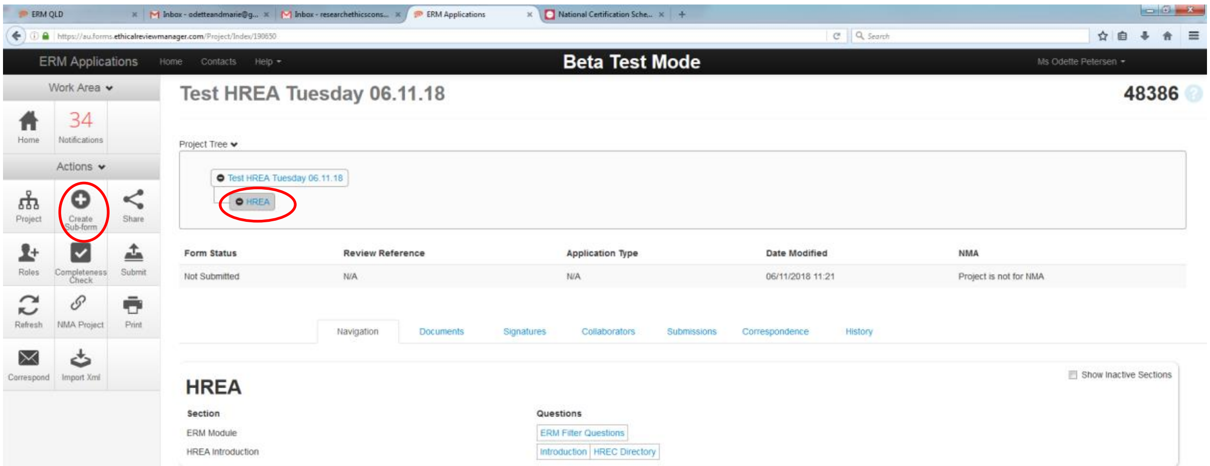
Create Sub-Form

Until you have received HREC approval the only sub-form that can be created is the site specific assessment form (SSA). Until you have submitted your main form (HREA / LNR) you cannot submit a sub-form (SSA). Following HREC approval other sub-forms become available such as amendments and progress reports.

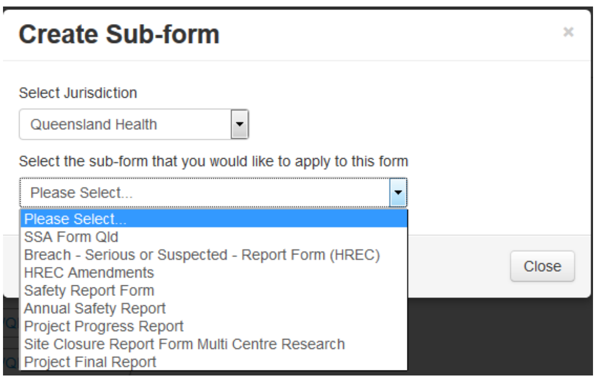


With the **HREC Ethics application highlighted in grey** (screen shot below), click **Create Sub-Form** action button i.e. Amendment, Report. Complete and submit the sub-form in the same manner as the Main Form. *It is really important to note, if you are submitting to the HREC you must have highlighed in grey the HREA or (DM HREC for an imported study from AURED). If you are submitting an amendment or report to a Research Governance Office you must highlight the SSA in grey or (SSA MDF for an imported study from AURED).*

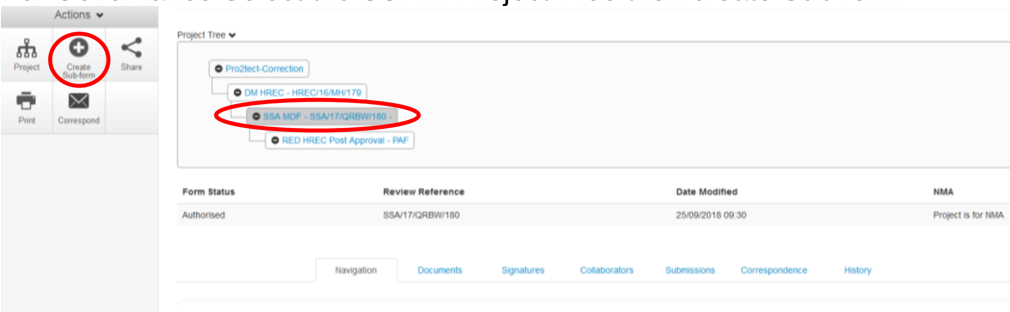
***Note**: Signatures are not required for Progress Reports.

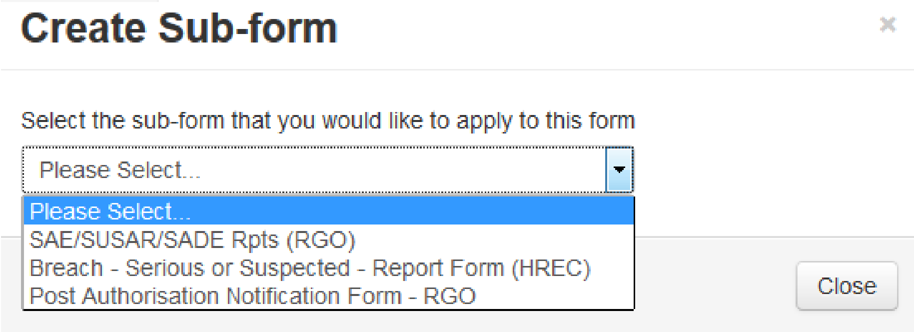


The dropdown menu displays your choices.



For Governance Select the SSA in Project Tree then create Sub-form.

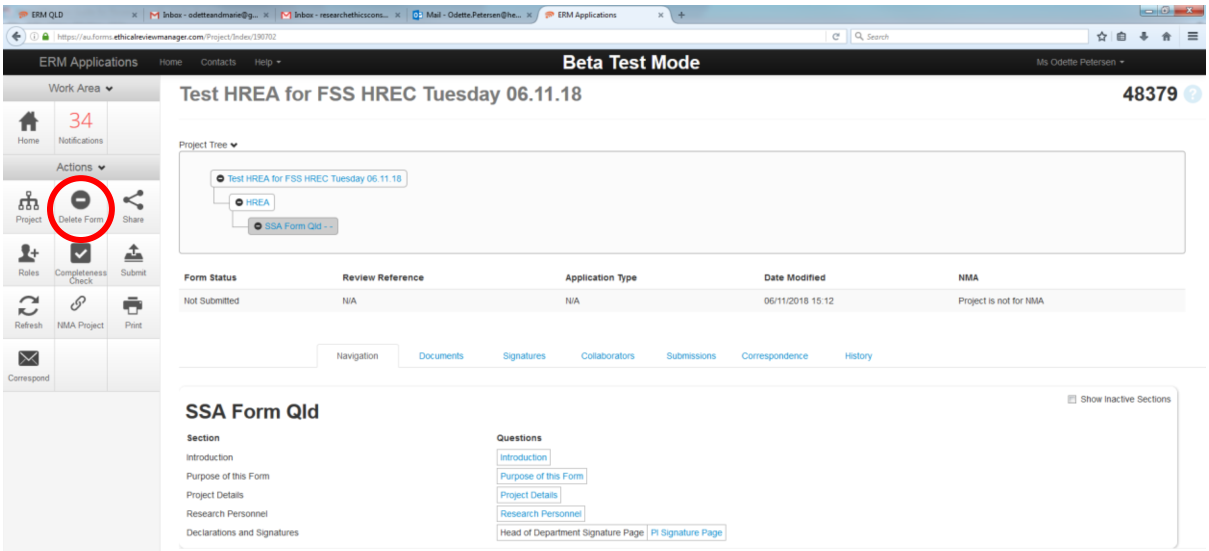




Complete and submit.

Delete Form

On a sub-form you also have the option to **Delete Form** prior to submitting. Highlight the sub-form you wish to delete, then click the **delete form.**



Forms returned for Further Information

If the HREC or RGO Offices request further information, the form will now be unlocked so you can update, amend and attach supporting documents.

- Respond to questions within your application form. **Do not use** the **Correspond** action. **Do not create** a sub-form to submit your response.

- Upload amended versions of PICFs/ Protocols within the application form.
- Provide both tracked change and clean copies including new version numbers and dates in the footer of these documents.
- Sign the new version of the application.
- Submit the application.

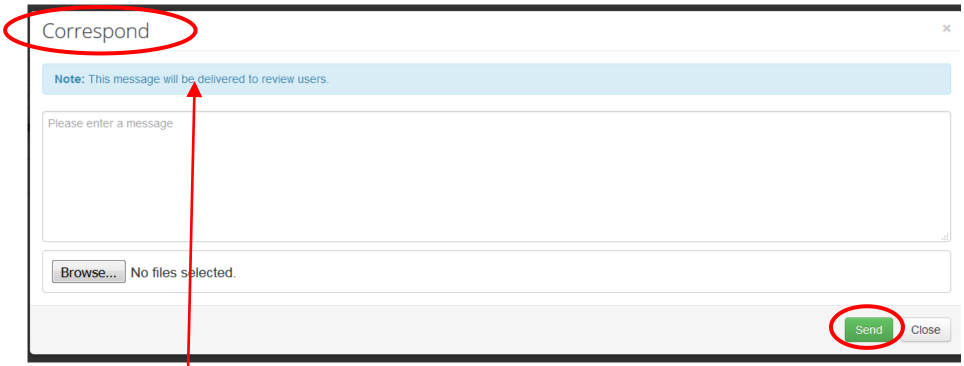
Roles vs Sharing

Roles allows you to share the HREA and sub-forms with a collaborator. You can select from a list of pre-defined roles.

The Share action button allows you to share a specific form with a collaborator. You can select required permissions. If this is a sub-form and you only share the sub-form, they will not be able to see the original approved HREA and attachments. This may become problematic in submitting site requirements. Qld Health recommends only using "Roles" to ensure your collaborators have appropriate control over their site and so they can see documents approved by the reviewing HREC.

Correspondence

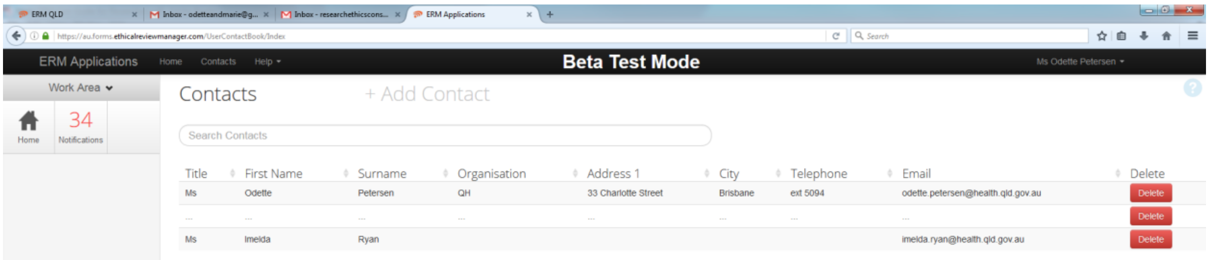
Your HREC or RG Office might instruct you to respond to a question using the **Correspond** action button.



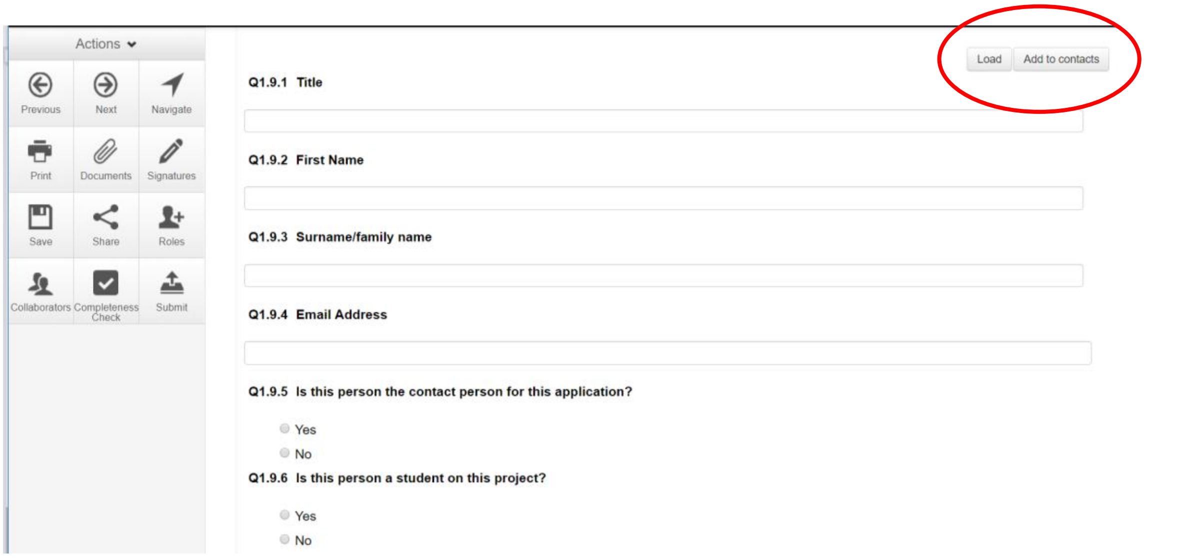
- The blue note in the Correspond box alerts you who will be notified in ERM when you press **Send**.
- Enter your message in the box and attach a document if requested. When you send the receiver will see a **Notification** in their **Notifications** tile.
- *Do not use Correspond to submit "response to request for further information"*.

Contacts

- You can keep your personal list of Contacts in ERM.
- Click on the Contacts menu item in the top menu bar (black).
- You can add new Contacts in here.



- 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. See screen shot below.



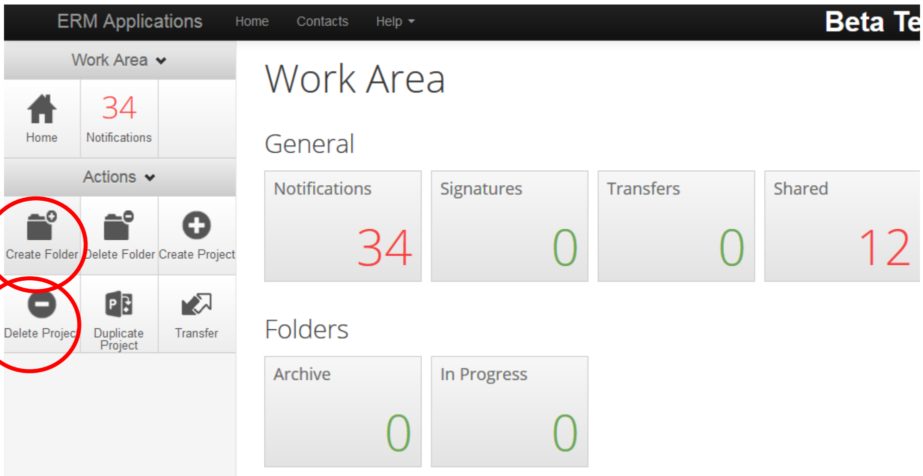
Once you have added a research associate to your Contact List, you can update their details at any time using the black menu bar at the top of the screen. Click **Contacts** and make amendments. The next time you **load** this contact to a new application form, their current details will appear.

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.

**If you create folders to store active research studies, when searching for an existing project you will also have to search in each individual folder to find your project.*

- You can also rename and delete folders.



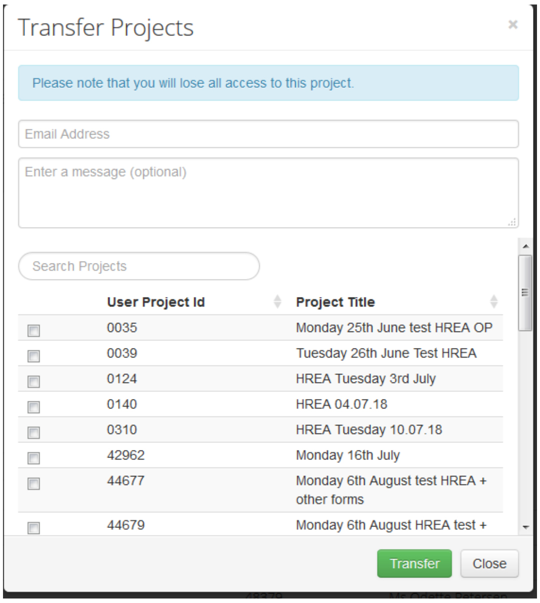
Delete Project

You can delete a Project if it contains no submitted Forms. This is handy if you have entered an incorrect Project title and realise this before you submit any forms.

Duplicate Project

- To duplicate a Project, ensure you are in the general work area screen.
- 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 however any documents uploaded to the original forms are not included.
- Click on the duplicate project tile, and follow the prompts. You will need to give the duplicated project a new name

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 or going on leave, you will need to transfer the Project in ERM 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 the project, the new project owner must already be in the system.

Main Forms

- HREA – select this form for all Human Research Ethics applications requiring full HREC review – i.e. not low risk research.
- LNR – select this form for low risk research, research that may be exempt and projects that may be exempt because they are not recognised as research as outlined in the National Statement e.g. quality assurance activity, audit of practice against current standards, service evaluation.
- MDF – select this form when your study has been reviewed by a HREC that doesn't use ERM and you are submitting an SSA.

Pre-defined permissions of Roles on the HREA

- HREA Share (read only) – allows collaborator the HREA only
- HREA Share (read, write) – in addition to viewing, provides the collaborator with write access to the HREA
- HREA Share (read, create sub-forms) – in addition to viewing and updating, provides the collaborator with the ability to create sub-forms and receive notifications
- HREA Share (read, submit, share, create sub-forms) – in addition to the above, allows the collaborator to submit forms and share the HREA with others