ecart

Ethics Committee on
Assisted Reproductive Technology

ethics rm

User Manual

Version: 0.01 Date:12.02.2024

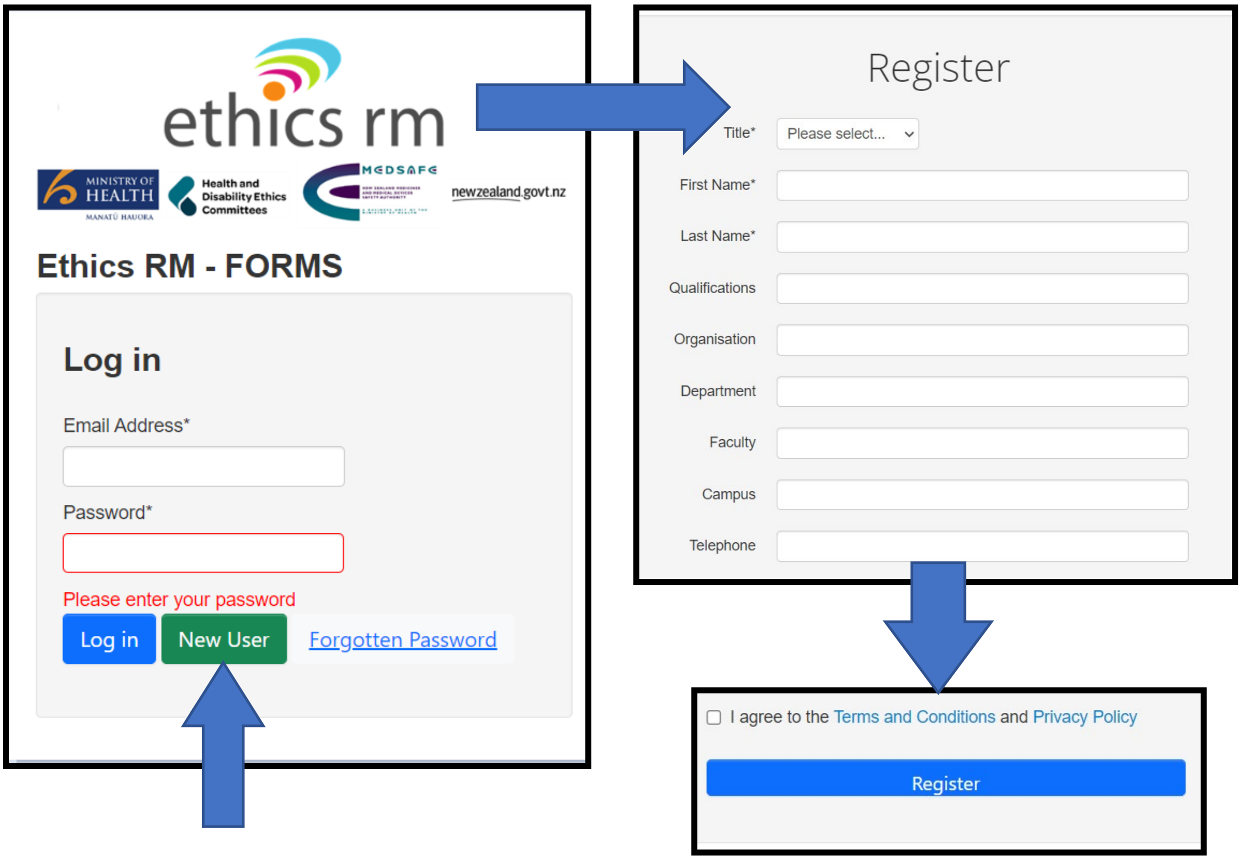
I would like to:

1. Create an account in Ethics RM

Ethics RM is a website that enables users to complete and submit applications to the Health and Disability Ethics Committees (HDECs), Ethics Committee on Assisted Reproductive Technology (ECART) and the Standing Committee on Therapeutic Trials (SCOTT).

Go to Ethics RM (https://nz.forms.ethicalreviewmanager.com)
Click Log in on the top right corner of the page (the Log in button allows you to create an account).

This will lead to a screen allowing for the input of log in information. To create an account, please click the “New User” button (as below). This will direct you to a registration page where you can input your details in order to create an account (also below).



Enter your details, choose a password and click “Register” after reading and accepting the Terms of Conditions and Privacy Policy. You will receive an activation email to your specified email address.

Note: Passwords must be 10+ characters long (but no longer than 64) and must contain both upper and lowercase letters as well as at least one special character and number. Please check your spam folder if the email does not appear in your inbox.

Click the link in your email to finish activating your account. Your account will not function until this step has been completed.

You may now log in with your email address and password.

If you receive an error message when creating your account, please try logging in with the email and password used to create the account anyway. If this does not work, then please email ethicsrm@health.govt.nz for troubleshooting assistance.

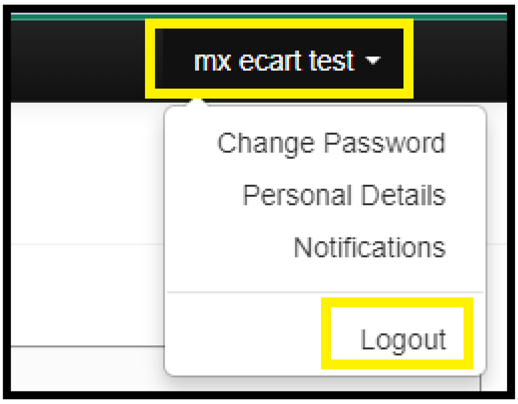
2. Log in to my Ethics RM account, and manage my account details or recover my account

Logging in and Out

If you have already registered for Ethics RM then you can go to the log in page: (https://nz.forms.ethicalreviewmanager.com)

From there you click the “Log in” on the top right corner of the page, enter your email and password and then click blue “Log in” button.

This will take you to the Work Area, this is the main screen for accessing Ethics RM. From here you can log out at any time by clicking your name and email address in the top right of the screen and clicking the option in the drop-down to “Logout” (as below).



Manage account details

Click your name and email address on the top right of the screen (as above).

From there you can select:

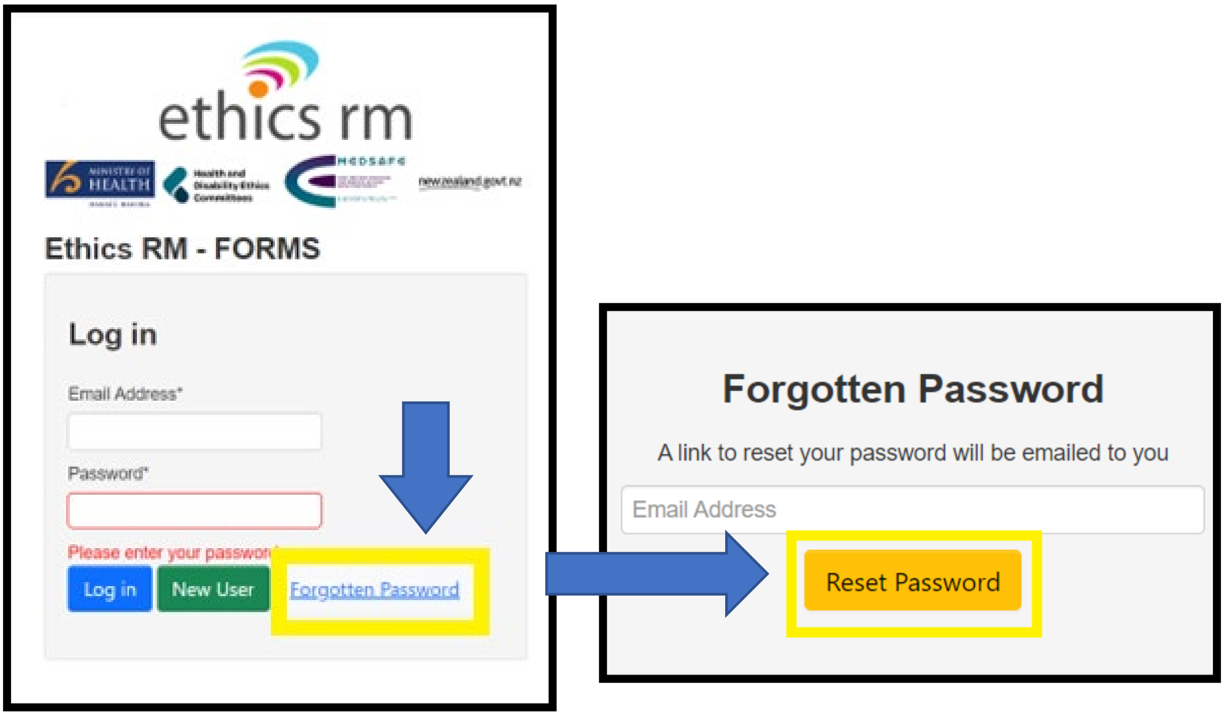
- Personal Details- to view or change your account details
- Notifications- which brings up information directly related to you and your projects
- Logout

Note: Notifications are also viewable under the notifications tile in the Work Area

Password Reset

If you cannot remember your password, please click Forgotten Password when you access the Log in screen. Please enter the email address you use for Ethics RM and click ‘Reset Password’ (as below).

Follow the instructions sent in your email to reset a new password. This will allow you to log in with your new password.



If you are having further issues with your account, please contact Technical Support (page 35). It is important to note that the Secretariat is unable to help with some account queries. Instead, support for technical issues is managed by Infonetica and may be escalated to them by the Secretariat.

3. Create, Edit or Delete Contacts

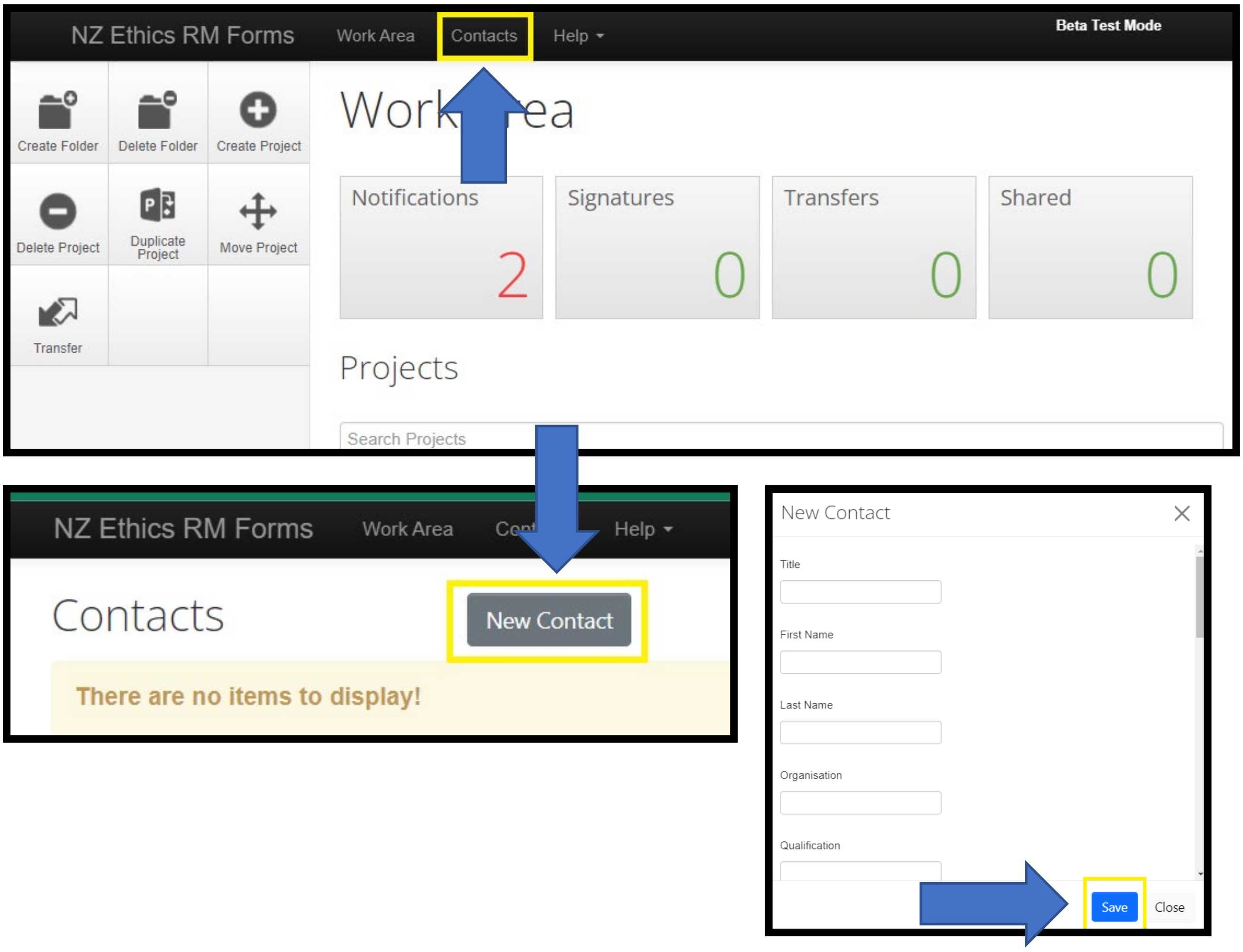
Your personal contact database is designed to help you if you are filling out many forms and often refer to a contact multiple times.

Create

To create a contact, click “Contacts” in the upper left of the page (as below):

From there you can:

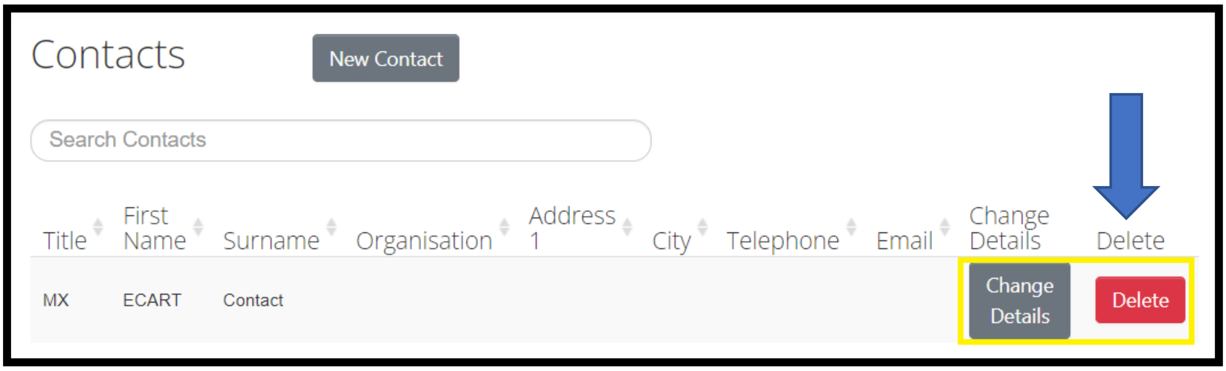
- Click “New Contact”
- Enter the details of your new contact
- Click “Save”

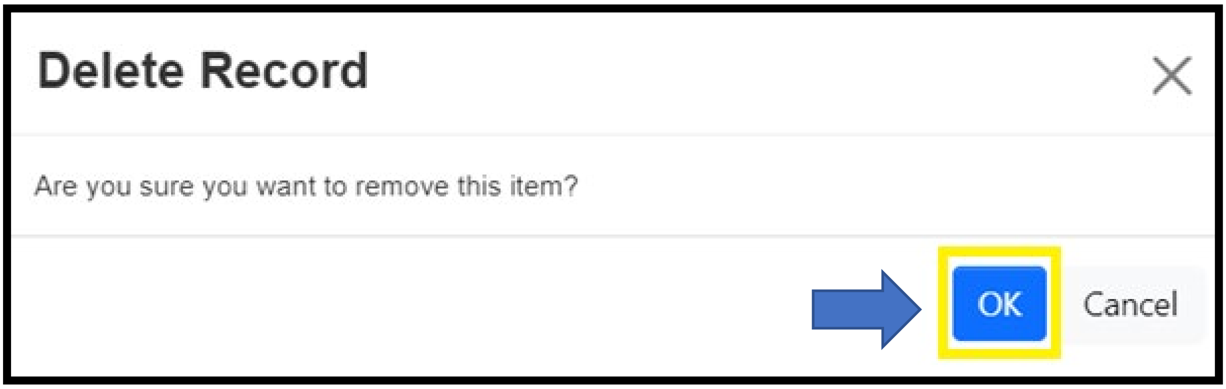


Edit

Existing contacts can be edited by clicking “Change Details”. Enter or adjust details then click “Save”.

To delete a contact, click the Delete button and then “OK” in the next screen (as below).

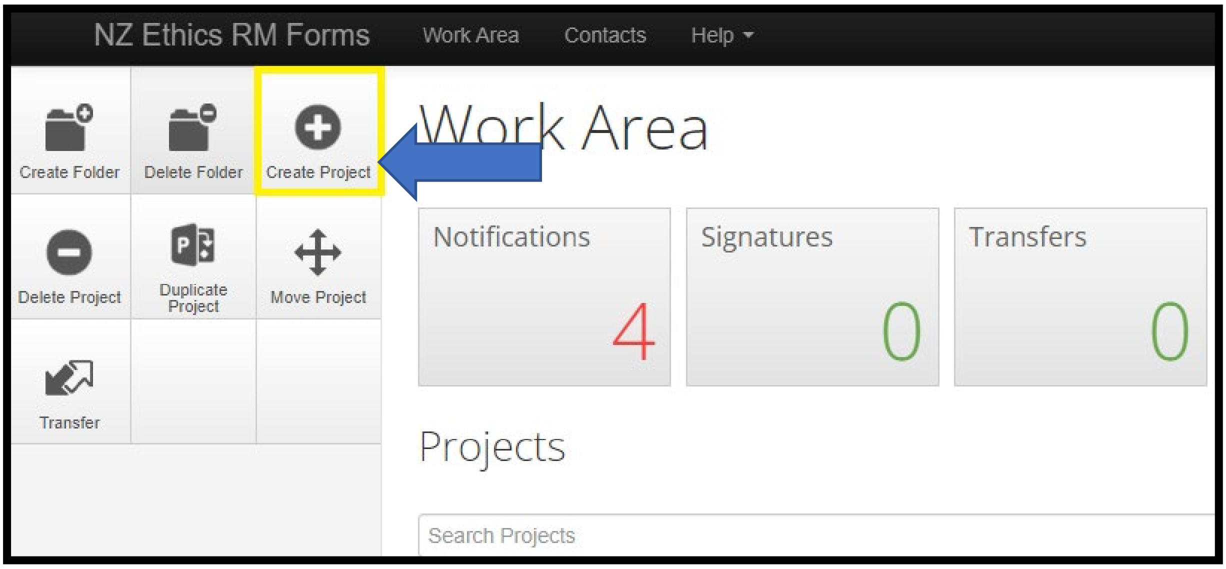




4. Create a new project

A project consists of one main form, this is your submission of an application for ARP to ECART for approval. Alongside this you may have additional forms submitted to respond to requests from the Committee. These are referred to RFI (Request for Information) sub-forms in Ethics RM and are forms that are submitted after approval.

In the Work Area of Ethics RM, click the Create Project button on the left side of the page.

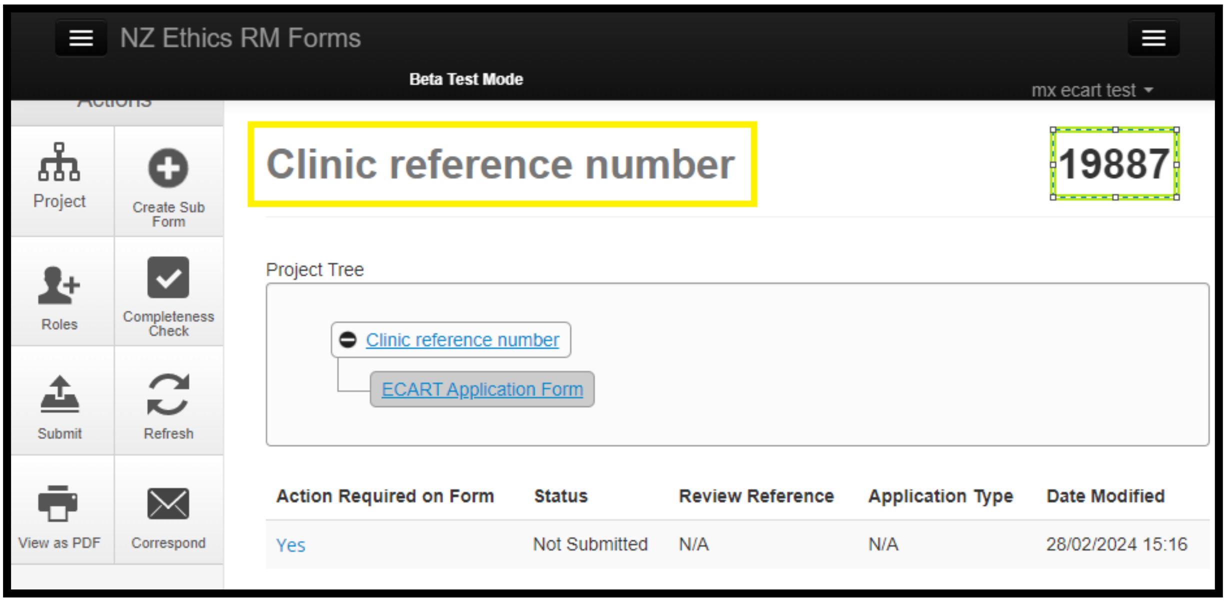


Enter your Project Title and select which application you wish to make from the options under Form.

It is important to note that Project Titles cannot be amended once created.

Please ensure that you name the project as you wish it to appear in Ethics RM. It is recommended that you name the application with the clinic reference number as this will make it easier for your tracking.
Click Create when you have finalised your project title and have the correct form selected.

Your new project will appear on the screen with a title (left) and Project ID (right). This can be found also under your Work Area if you have to navigate off this screen.



Only the project owner currently has access to this form until further collaborators are added. For specific instructions please see Section 10 – Allocate Roles (page 23) and set up email notifications for a project.

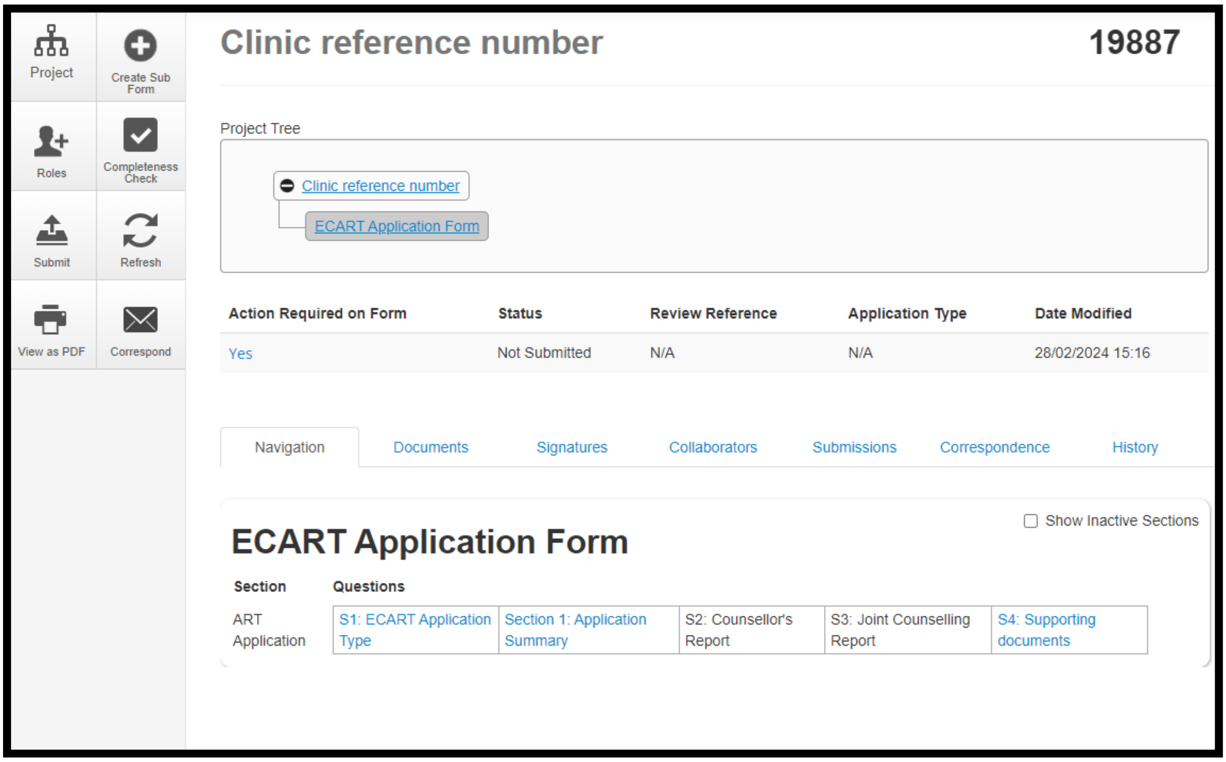
The project tree will currently only contain the chosen application form. Post approval items will appear under this form after these items are submitted in future. Later you will also be able to view this by clicking Project on the left side to see the Project Overview.

The row beneath the project tree allows you to see if an action is required on the form, its status, review reference, application type and date and time it was last edited.

Project tabs

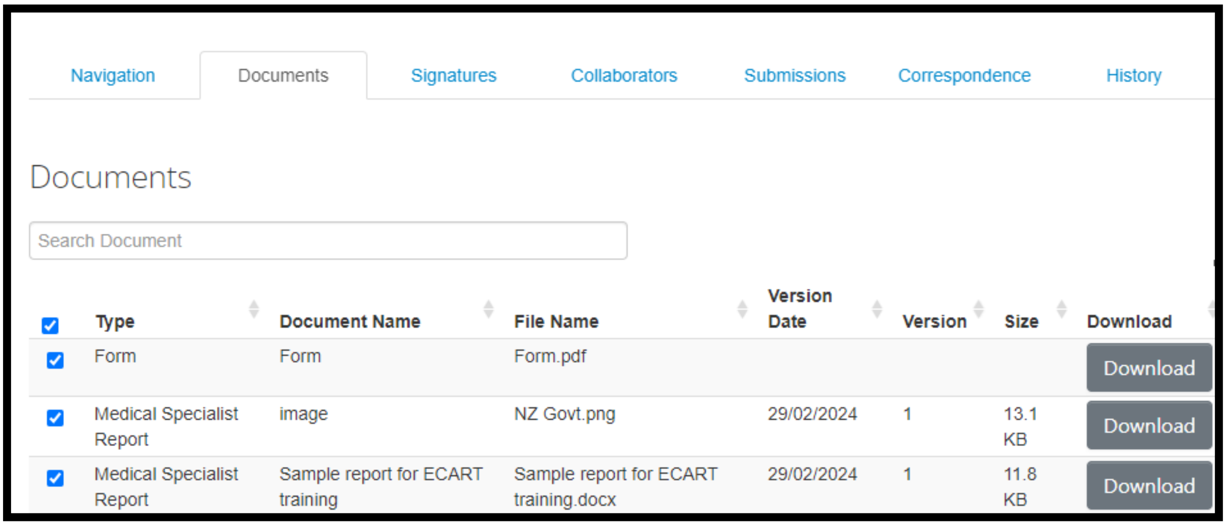
Navigation tab – selecting this tab gives you an overview of the sections of the form you have created for the project. The tick box in the top right corner of the form allows you to only see sections currently inactive based on the answers in the form.

Inactive questions are not the same as incomplete questions, because the form removes or adds some questions based on your answers. Therefore, you may not need to complete every section of the form.



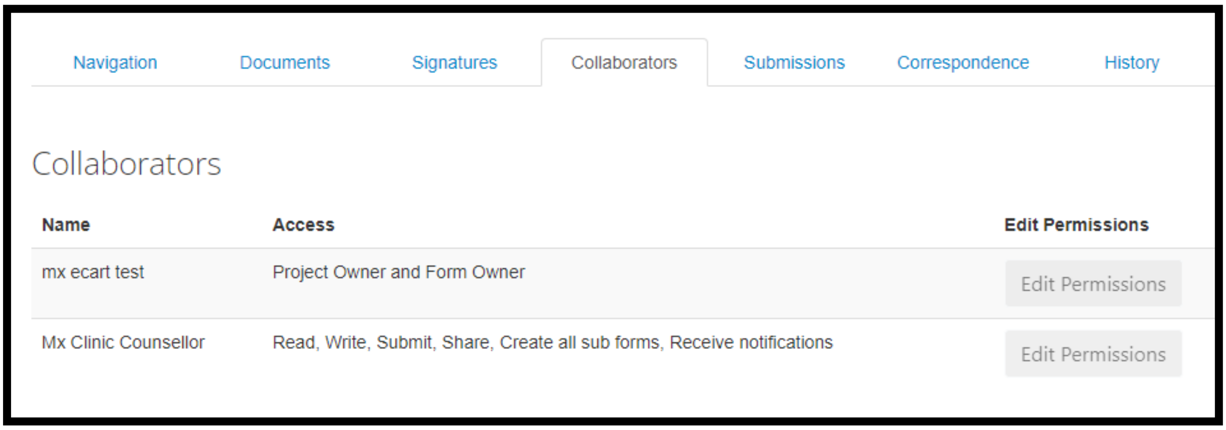
More information about using the navigation tab to complete your application is provided in the next chapter (page 16).

Documents tab – selecting this tab shows which documents are currently attached to the form. This tab provides a view-only of the documents, which means that it does not allow you to upload or change any documents attached, but you may choose to download the documents individually or in bulk (as a single PDF) by using the 'view selected' button.

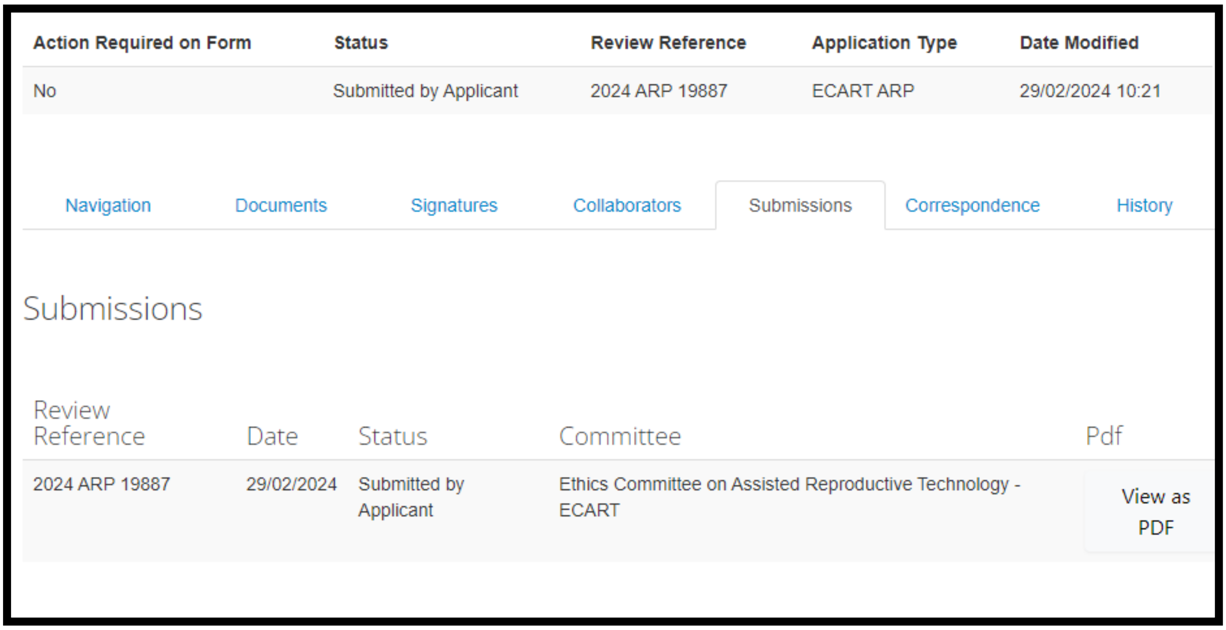


Signatures tab – selecting this tab shows which signatures are active on the form (under the heading 'Signatures', as well as which requests are pending (under the heading 'Signature Requests'). This will largely not be used in ECART applications but is something that is typically used in HDEC and SCOTT applications that ERM are also used for.

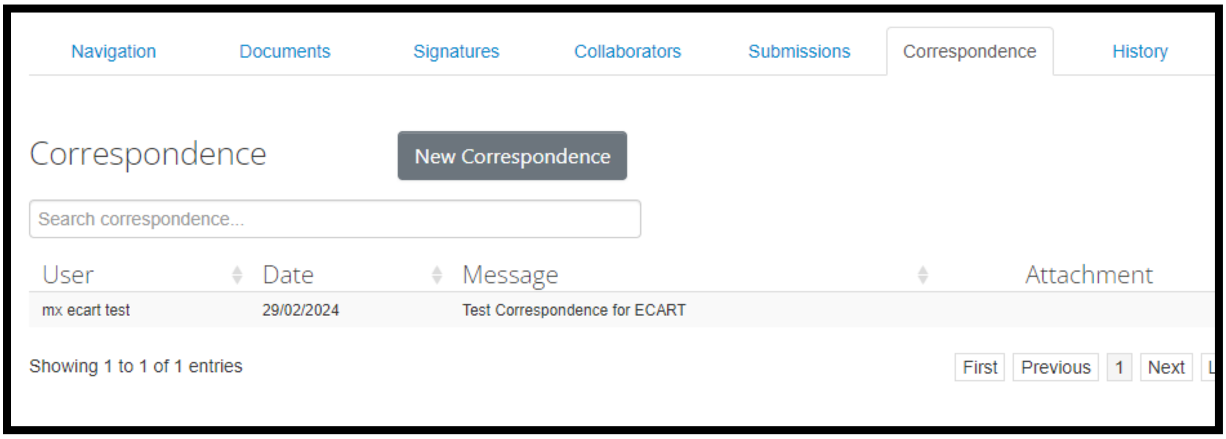
Collaborators tab – selecting this tab shows the name and type of access linked to each collaborator added to the form. The project owner may edit permissions for existing collaborators here. New collaborators can be added through the Roles function (page 23).

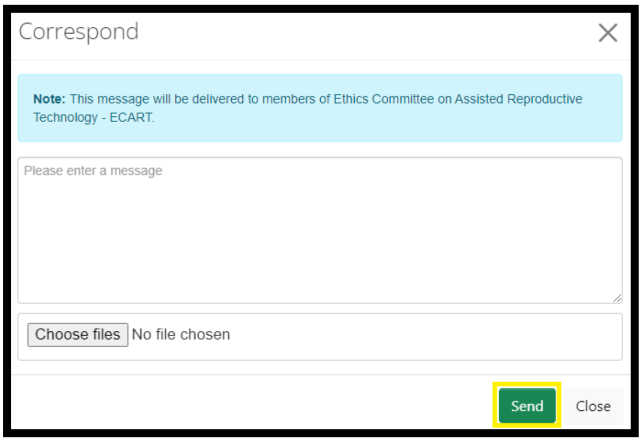


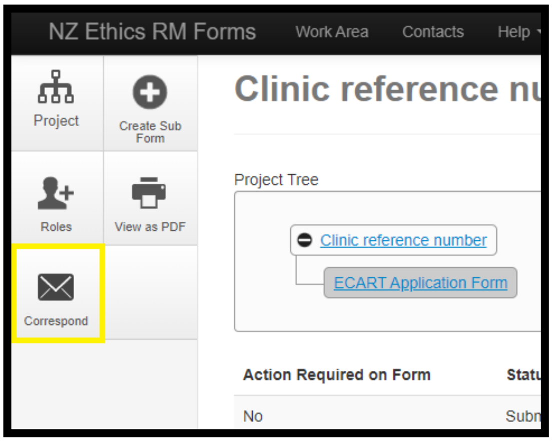
Submissions tab – selecting this tab gives you a timeline of the submission of the form. Each time it is submitted, it will appear here.



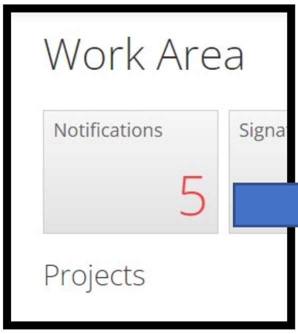
Correspondence tab – selecting this tab allows you to directly send a message to the Secretariat. Message history (both received and sent) will display here with timestamps. You can also send correspondence using the 'Correspond' button on the left-hand side of the window.

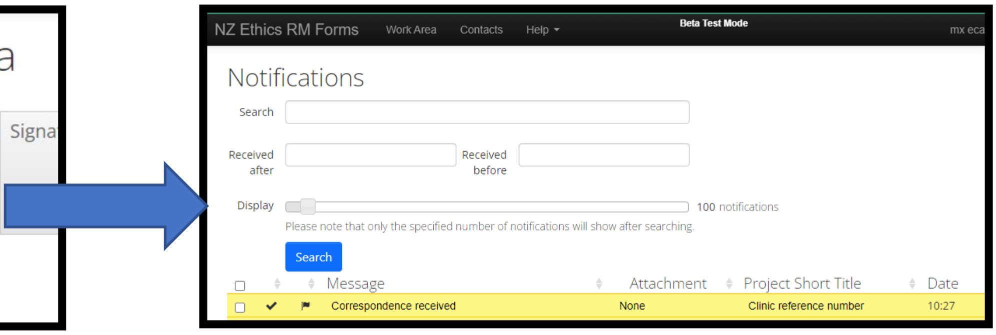


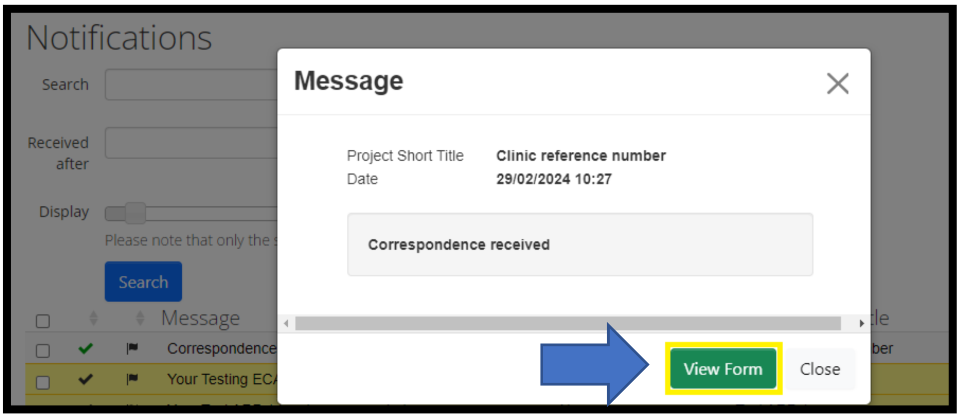




You will receive a notification in Ethics RM to alert you when there is a response. Clicking on a notification will display a shortcut to the form associated with the correspondence. Click View Form to go to the form the message has been received for.

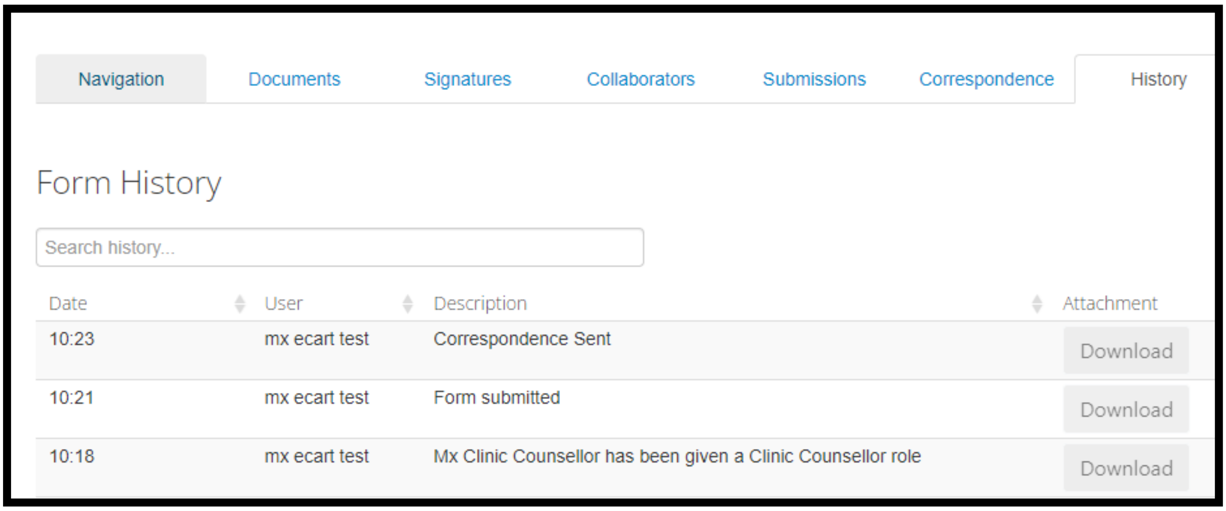






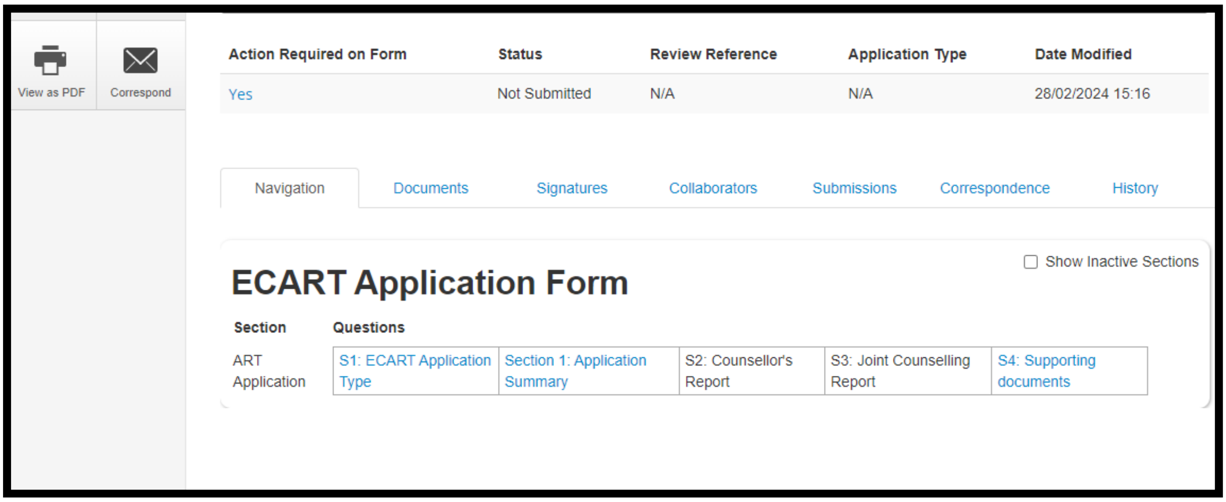
File attachments can be sent via correspondence but please **do not send additional or missed documents that were not included in your submission.** These will not be reviewed or included in the agenda for meetings.

History tab – selecting this tab shows the full history of the submission, including actions and decisions by both the project owner and the Secretariat.



5. Complete the form

The ‘Navigation’ tab allows you to navigate through the form by Questions under each Section. Inactive questions are not displayed unless you tick Show Inactive Sections. Active questions automatically display, clicking on them will take you directly to that question in the form. Certain questions are activated or deactivated depending on your answers to the questions in the form, so not all pages of the form will be active, and it is important you answer everything accurately to generate all relevant questions.

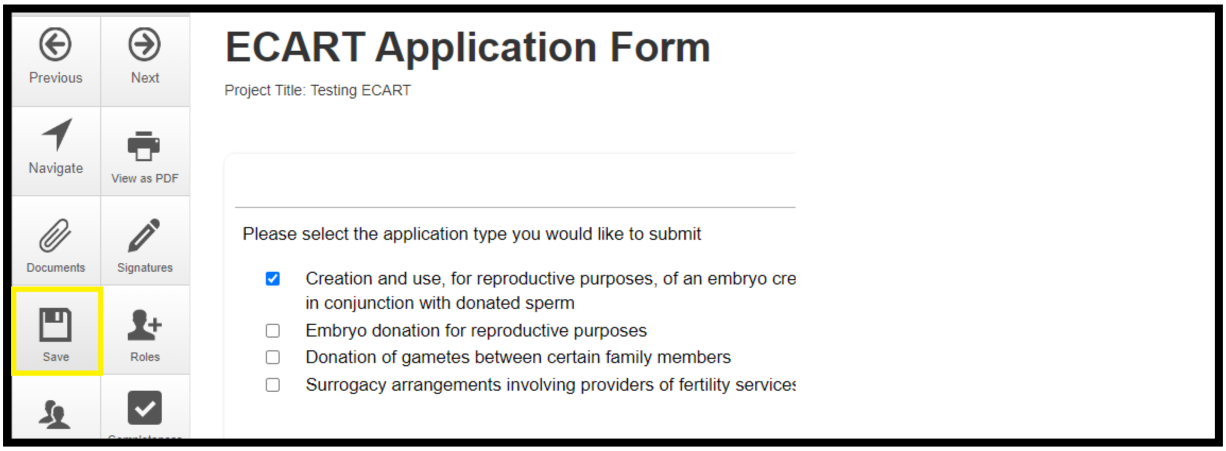


The form does not need to be completed in one session as there is a save button you can click at any time.

Clicking ‘Navigate’ in the form brings you back to the project main screen.

To fill out the form, click the first question available for you to fill out. From there, you can proceed with filling in the form. If there are multiple pages, you may click Previous or Next on the left-side menu, as well as Previous Page and Next Page at the bottom of each page.

Click Save on the left-side menu if you wish to Save your progress at any time and navigate out of the form. You may return to certain sections using the Navigation tab from the project main screen.

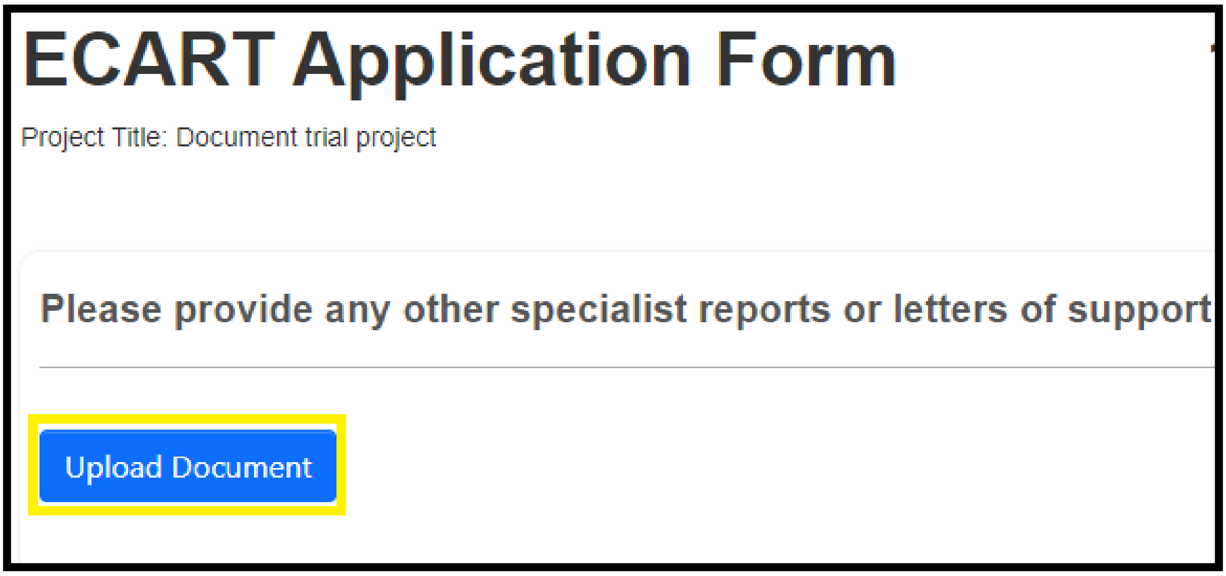


Upload documents

Questions within the form will prompt you when you need to upload documents in relevant sections. These will be attached to the form and appear under Documents tab for your reference (and re-download if required).

You will need to upload one document at a time if multiple attachments are required.

While the form should prompt for all that are required, you remain responsible for ensuring you have attached everything required as per the Committee's requirements. Your submission may be considered invalid if mandatory documents are missing due to an error in submission.



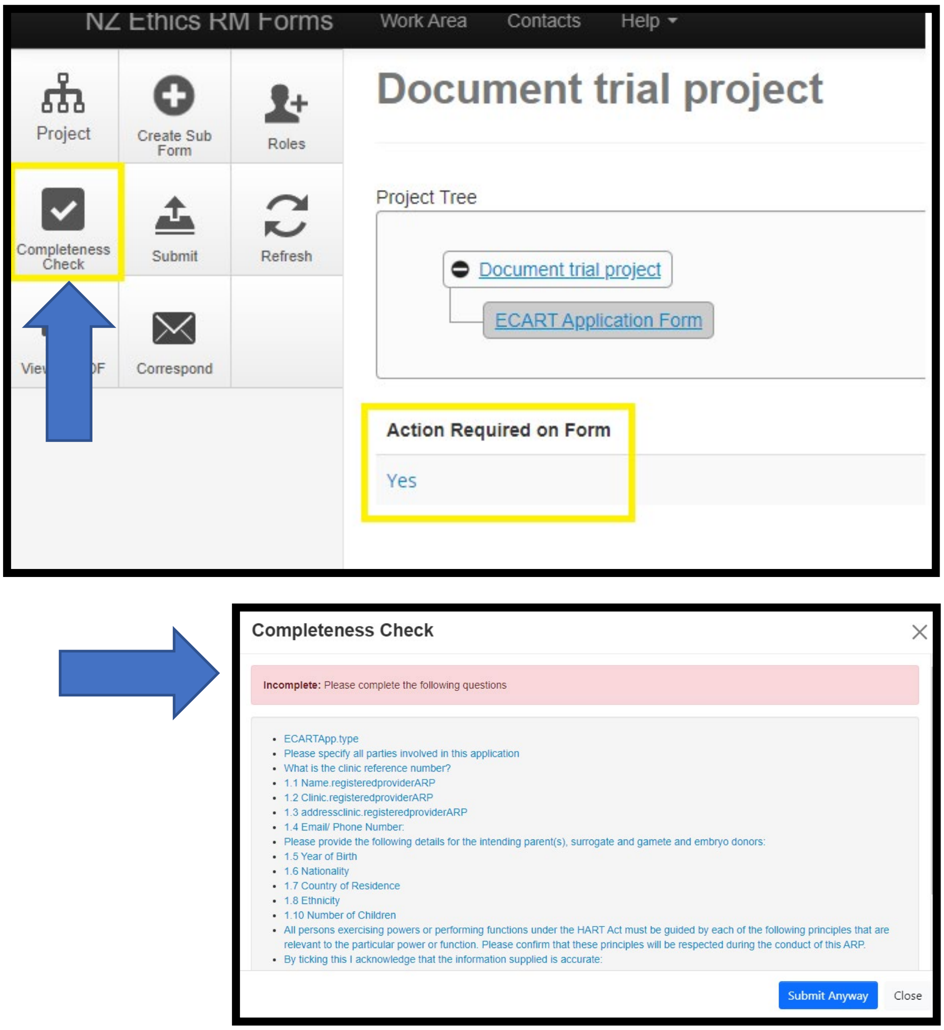
6. Check for Completeness

It is important to check for completeness before you submit to make sure you have answered all the questions in the form.

While in the form or selecting the submission in the project tree in the main page of the project, click Completeness Check from the menu on the left of the screen to identify missing information from your application. Any outstanding items will be listed. You can select the highlighted questions to go to that section to complete them. Any sections that require signatures will also show up as incomplete if they are not yet signed.

You have the option to submit anyway, but we do not recommend this as a form is considered incomplete and will not be validated if it is missing sections. This will cause delays for your submission.

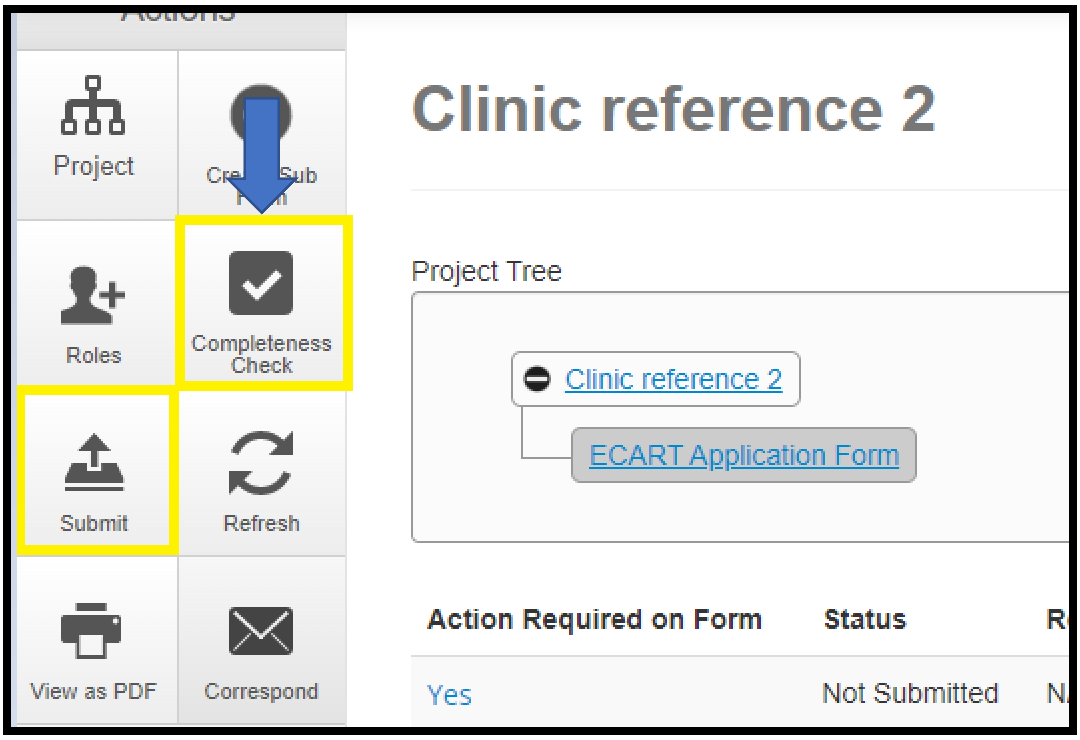
Once the application is complete, the check for completeness will say 'Your form is complete and ready to submit'.

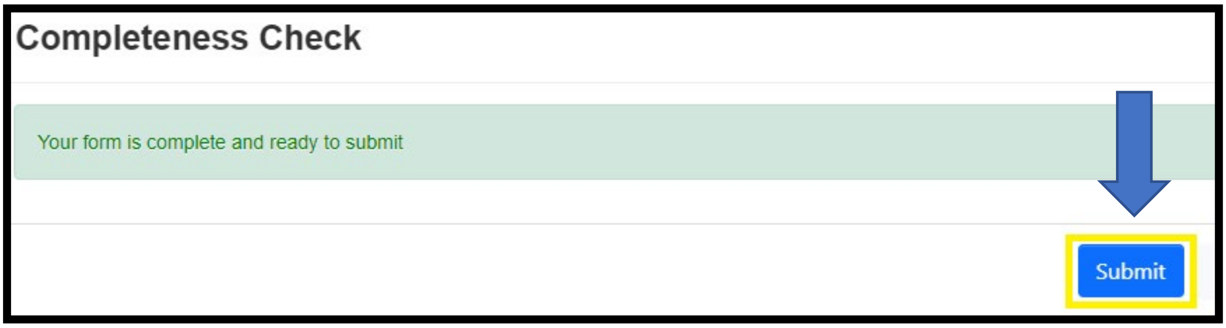


7. Submit a form

Once you have completed the form and uploaded the relevant documents, you can submit your application to ECART.

You can do this by either clicking Submit after doing a completeness check, or by clicking the Submit button on the left-side menu. Once you have submitted your form, you will be taken to a confirmation screen that confirms your submission as complete.





NZ Ethics RM Forms

Beta Test Mode

mx ecart test

Submission Message

Thank you for submitting your form. It has been successfully received.

What happens next?

If you have submitted to HDEC:

If your study is out of scope for HDEC review, you will receive an automatically generated out of scope letter.

Please note that this does not mean that your study has HDEC approval or that it does not require ethics approval - only that it does not require HDEC approval.

If your study is within scope for HDEC review, the HDEC Secretariat will assess your application and, if valid, assign it to either the full or expedited review pathway.

If your study requires full Committee review, you will receive a letter from the HDEC Secretariat providing the time and date of the Zoom meeting at which your application will be reviewed by HDEC. Study investigators are encouraged to attend these meetings.

If your study can be reviewed via the expedited review pathway, your application will be reviewed online by two HDEC members rather than in a full Committee meeting. Study investigators will not be present for this review.

If your study is not validated, you will be asked to update the information in your application before it can be assigned to a review pathway.

If you have submitted to ECART:

If you have submitted your application of an ARP to ECART you will receive a letter acknowledging your application and validating it from the ECART secretariat.

If there are any changes you wish to make to your application, please recall the form using the recall button in the work area.

Should there be any issues with the application please reach out to the ECART secretariat for assistance.

Back to Project | Print Submission to PDF

Please note that the information relevant to the ECART application process is after that for HDECs. We use the same system hence the presence of that information in this part of ERM.

8. Recalling applications

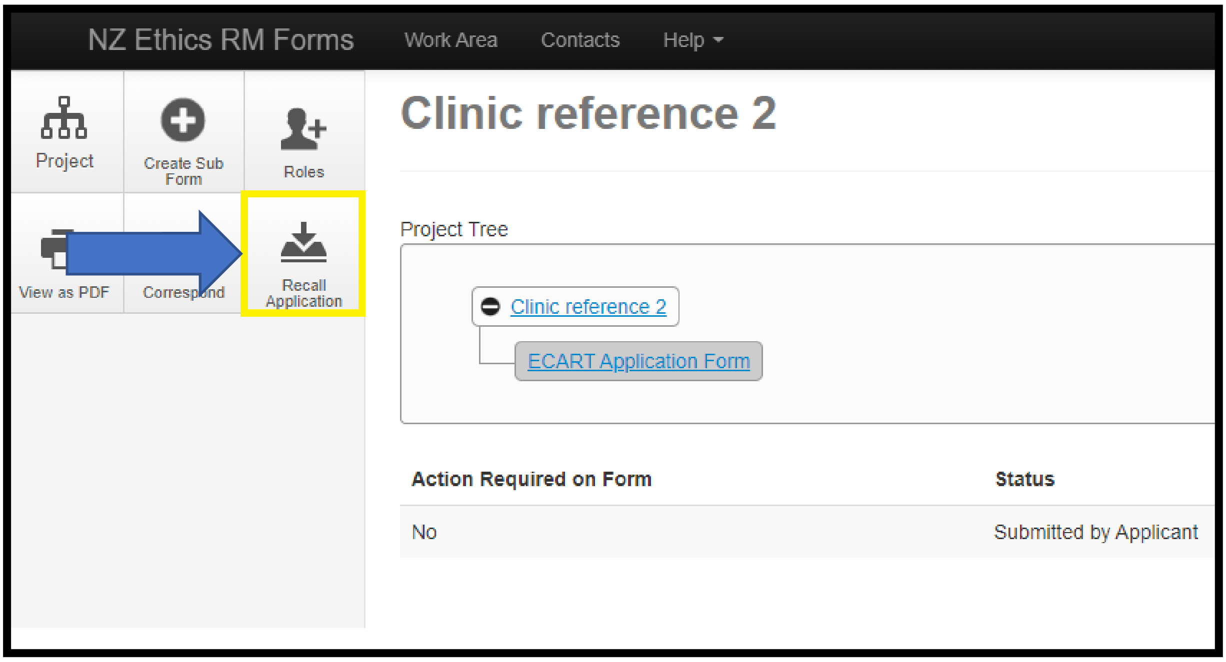
You cannot make changes to an application between submission and approval without recalling the application. This will pull the application back from out of being submitted and allow changes to be made. This will need to be followed up by resubmitting the application else the application will not be added to the Committee meeting's agenda.

This is also the process should documents be missing from the application.

Please note the recall option is only enabled if the application is pending registration by the review body (ie, the submission is awaiting the committee secretariat to validate the application). If your application has been successfully recalled you may amend the form, upload/amend your supporting documents and request signatures (if required) prior to re-submitting the application.

If you are not able to recall your application because it has been validated by the Secretariat and you would like to withdraw your application, you need to send correspondence to the Secretariat in Ethics RM or email in the ECART inbox requesting this.

To recall your submission, click the Recall button on the left-side of the window. Only a project owner or a user with 'Full write' access can perform this action.



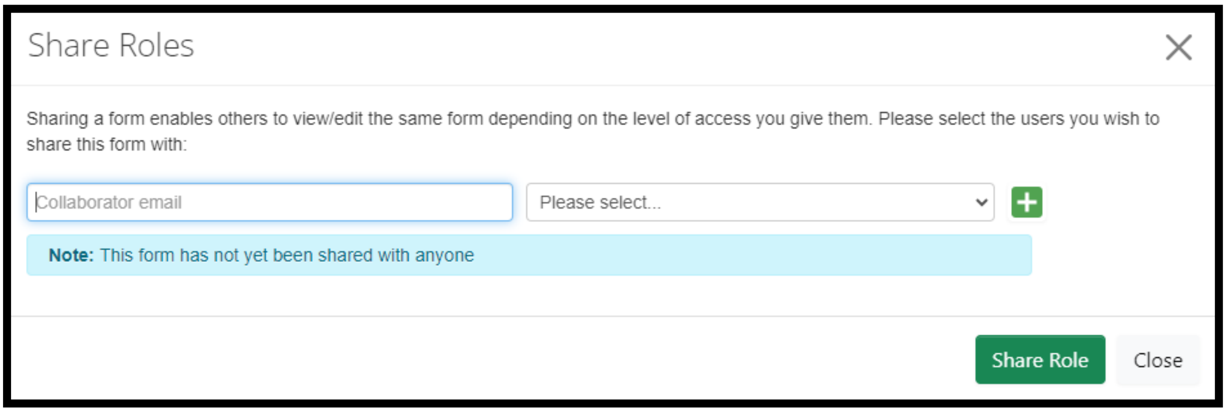
9. Allocate Roles/set up permissions and set up email notifications for a project

What are Roles?

Roles are a function where you can extend this access and add collaborators to your project and grant various permissions.

By default, only the **project owner** has ownership and permission to view and edit the application.

To add a Role to this project, click the Roles button on the left side of the window. Enter the email of the person you wish to invite to see this project under Collaborator email. This person must have a registered Ethics RM account. Select what access you wish to grant and click the green + sign to add the role. Repeat this as many times as you require, and you can assign multiple roles to a single user.



Click Share Role once you have added the collaborators.

You do not need to add the Secretariat to a role for them to be able to see or access your application after you submit.

A project owner can review permissions using the Collaborators tab or remove/edit permissions in future using the Roles button again.

Receiving email notifications

Email notifications are automatically sent to the application owner. If additional users need to be notified, ensure you assign them ‘Email Notifications’ when allocating roles to these users. Accounts with the ‘Email Notification’s’ role will receive copies of ECART decision letters via email.

10. Transfer a project to another user

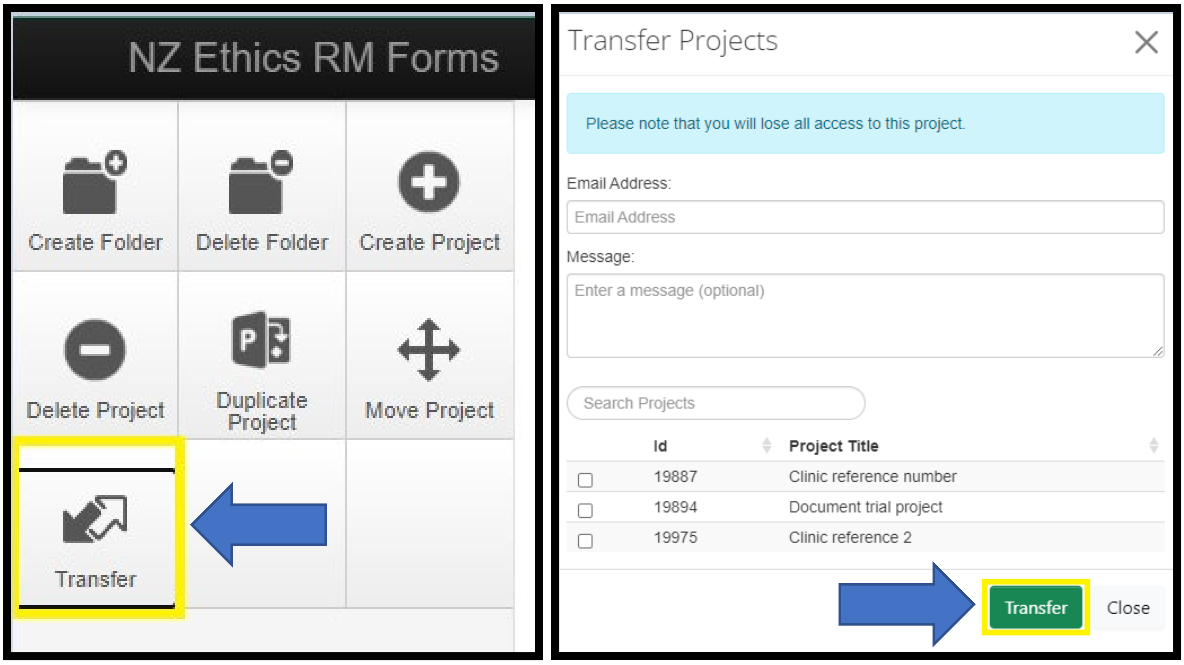
You can transfer a project if you would like to give somebody else full and permanent control of the project.

Once the form has been accepted by the recipient, you will no longer be the owner of the form and the person to whom the form was transferred will become the new project owner.

How to Transfer a project

Go to the Work Area. If the project you wish to transfer is in a folder, you must open that folder first.

Click on the Transfer button on the left-side of the window.

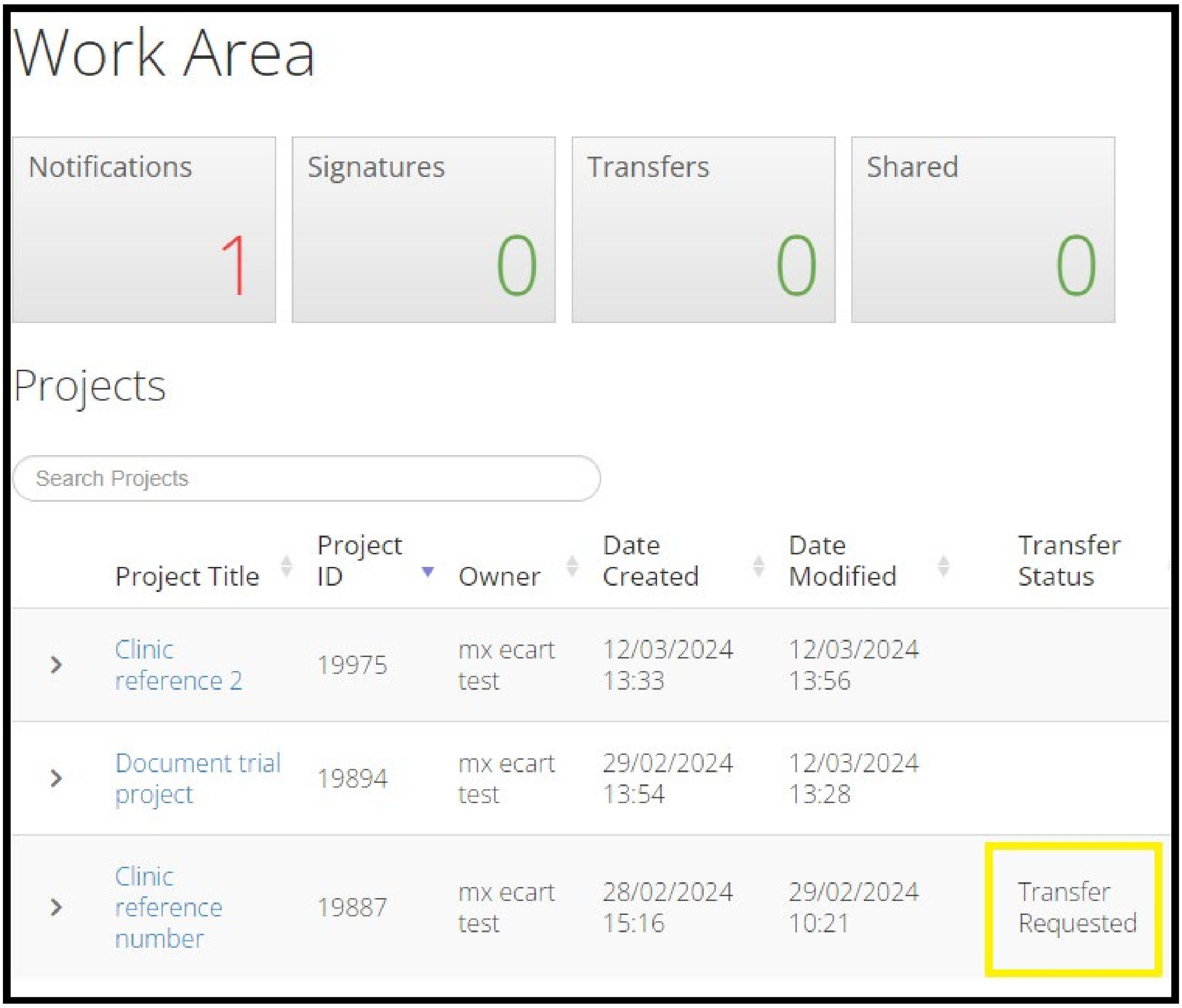


Enter the email address of the user you wish to transfer your application to. (Note that they must have an existing verified Ethics RM account for this to be valid.)

Enter a message to accompany the transfer request if you wish.

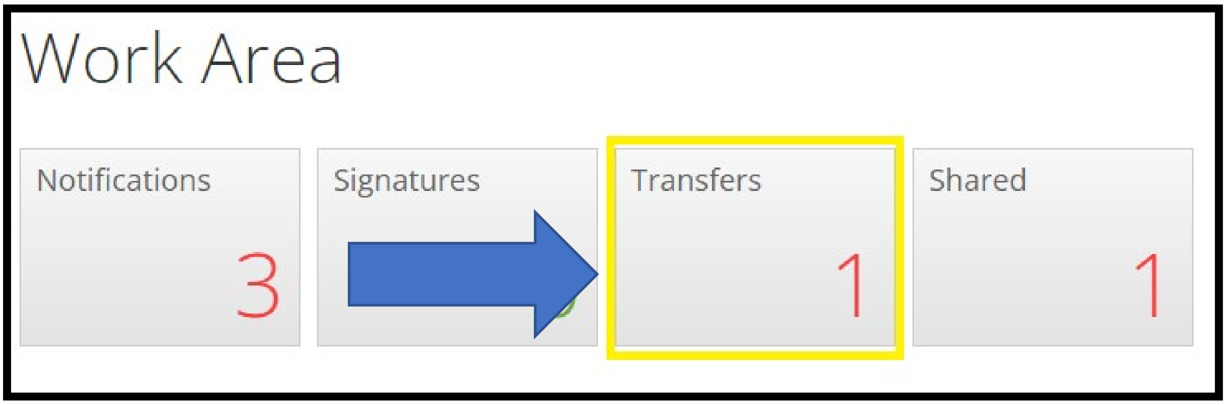
Select the project you wish to transfer. You may do this for multiple projects at a time. Click Transfer.

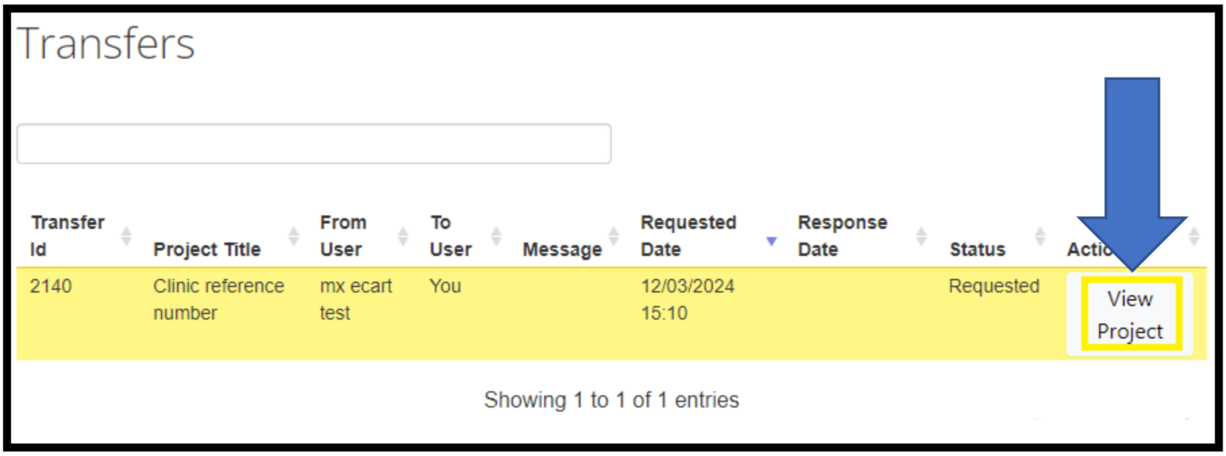
While the transfer request is pending the applications will remain in your work area.



How to accept a Transfer

Applications that have been transferred to you will appear on the main work area under the Transfers tile.





Click ‘View Project’ to be taken to the application. From here the application may be reviewed and the transfer accepted or declined by using the action menu to the left.

A pop-up will then ask you to confirm you wish to accept or reject the transfer.

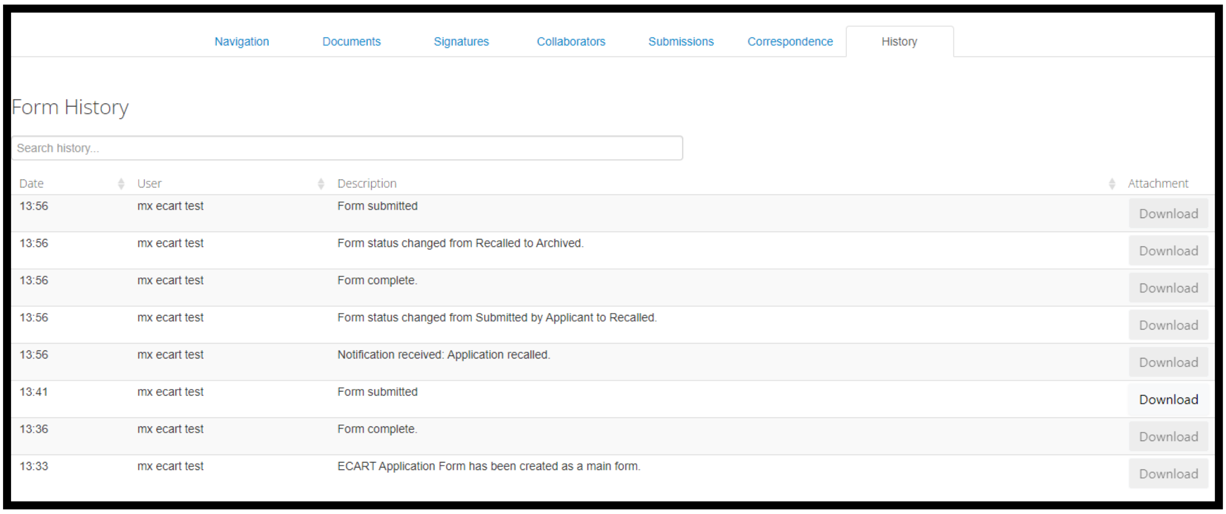
11. Follow the progress of my submission and view letters

There are two ways to keep track of an application's progress, via the history tab and via Ethics RM notifications.

History tab

In the History tab of your project, you can monitor the progress of your application through the key stages in the review process and view decisions from ECART.

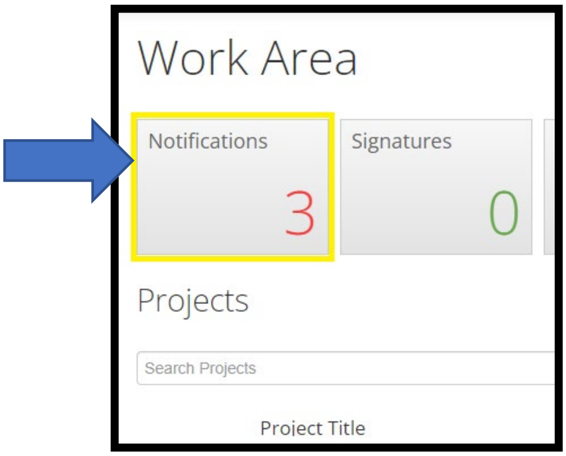
Letter from ECART, such as validation letters and decision letters, can also be viewed and downloaded here. If a letter is attached to an event the 'Download' button will be visible and the letter may be viewed here.

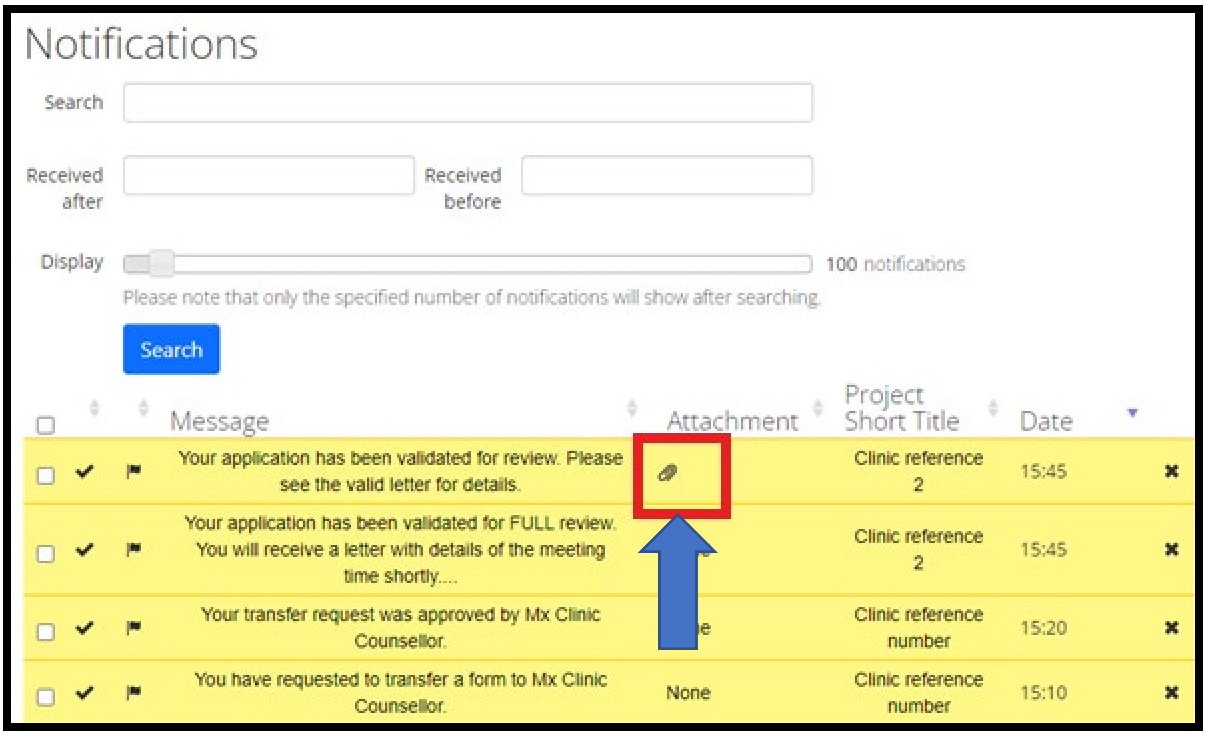


Date	User	Description	Attachment
13:56	mx ecart test	Form submitted	Download
13:56	mx ecart test	Form status changed from Recalled to Archived.	Download
13:56	mx ecart test	Form complete.	Download
13:56	mx ecart test	Form status changed from Submitted by Applicant to Recalled.	Download
13:56	mx ecart test	Notification received: Application recalled.	Download
13:41	mx ecart test	Form submitted	Download
13:36	mx ecart test	Form complete.	Download
13:33	mx ecart test	ECART Application Form has been created as a main form.	Download

Notifications Tile

The notifications tile will update whenever an action is taken on your study. A paperclip icon indicates a letter is attached to the notification. Clicking it will display the letter.




Notifications
Search
Received after
Received before
Display
100 notifications
Please note that only the specified number of notifications will show after searching.
Search
Message
Attachment
Project Short Title
Date
Your application has been validated for review. Please see the valid letter for details.
Clinic reference 2
15:45
Your application has been validated for FULL review. You will receive a letter with details of the meeting time shortly....
Clinic reference 2
15:45
Your transfer request was approved by Mx Clinic Counsellor.
Clinic reference number
15:20
You have requested to transfer a form to Mx Clinic Counsellor.
None
Clinic reference number
15:10

12. Duplicate or delete an application

The Work Area allows an application owner to duplicate the information in an application into a new one or to delete it. This can be useful if there are resubmission of applications to the Committee for any reason.

Duplicate a project

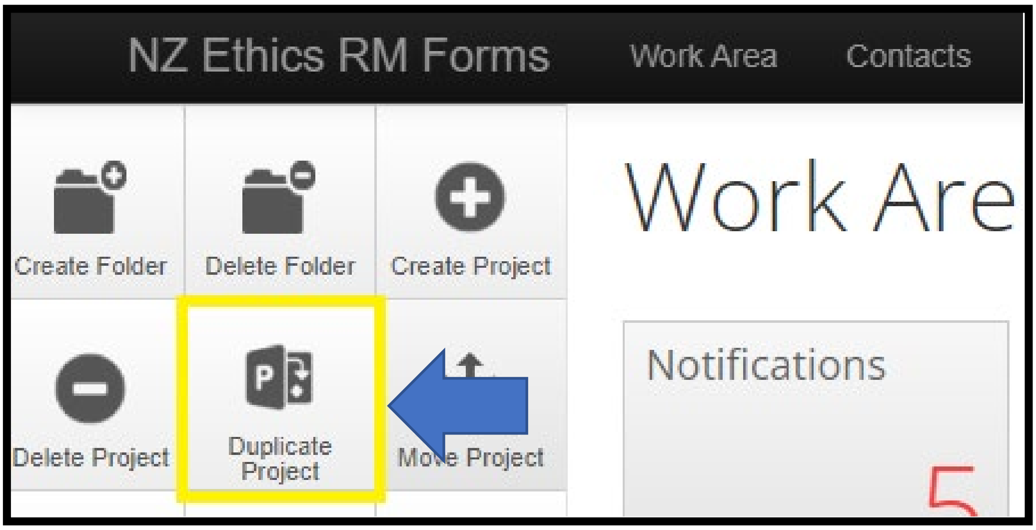
Click ‘Duplicate Project’ from the left side of the Work Area.

Select from the drop-down menu for the project you would like to duplicate.

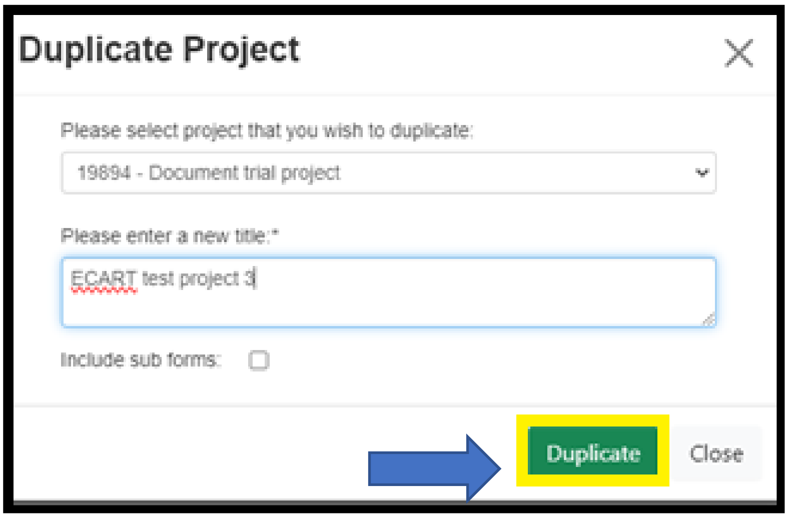
You will be required to select a new project title.

There is a tick that allows you to include Sub Forms. This is unlikely to be needed, especially if a project is being duplicated for resubmission.

Click Duplicate.



Delete a project

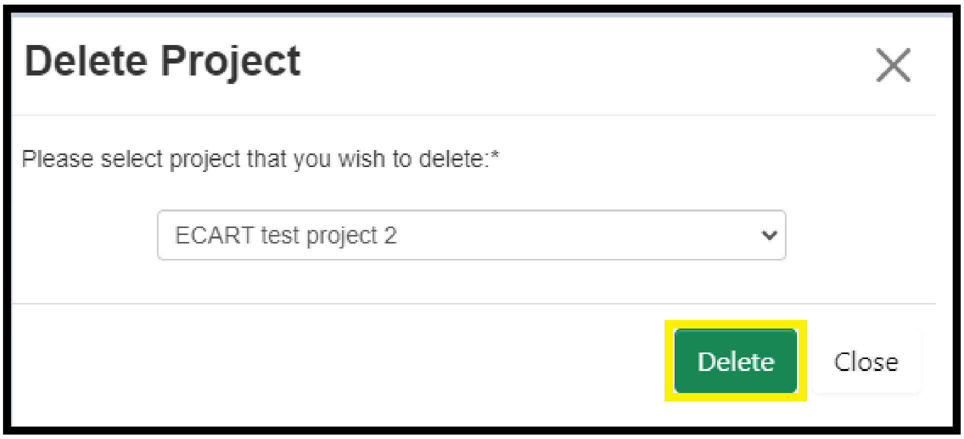


Click ‘Delete Project’ from the left side of the Work Area.

Select from the drop-down menu which project you would like to delete.
Click Delete.

After a confirmation prompt the project will be removed from your work area. Once a project has been deleted it **cannot be recovered.**

Note that a project cannot be deleted if it is under review. It must be recalled or withdrawn first to be deleted.

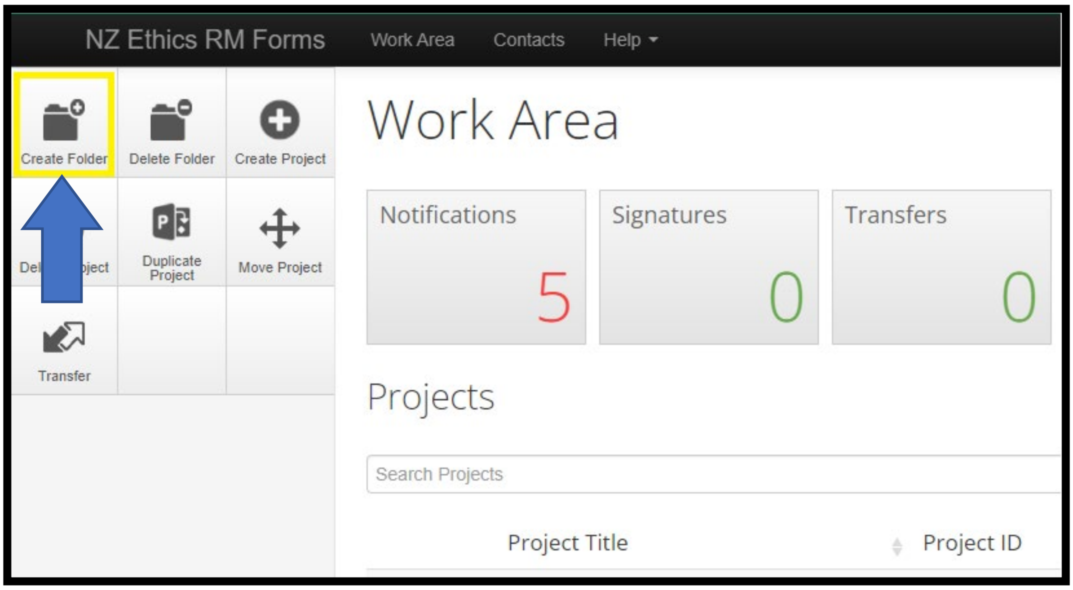


13. Manage Projects in the Work Area

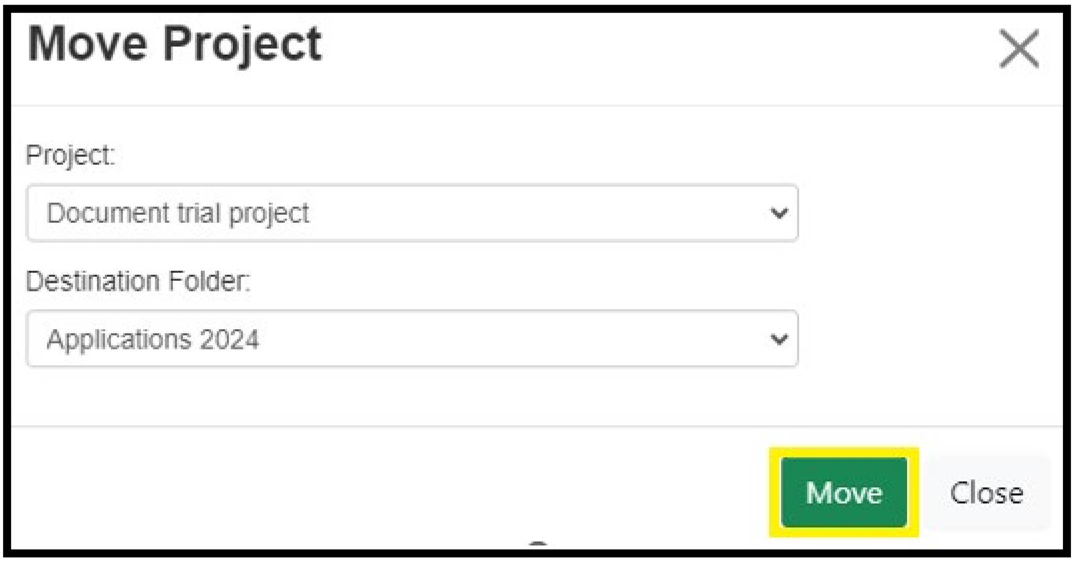
This section lists all the available categories you can store your projects in. This is similar to directories in a computer filing system.

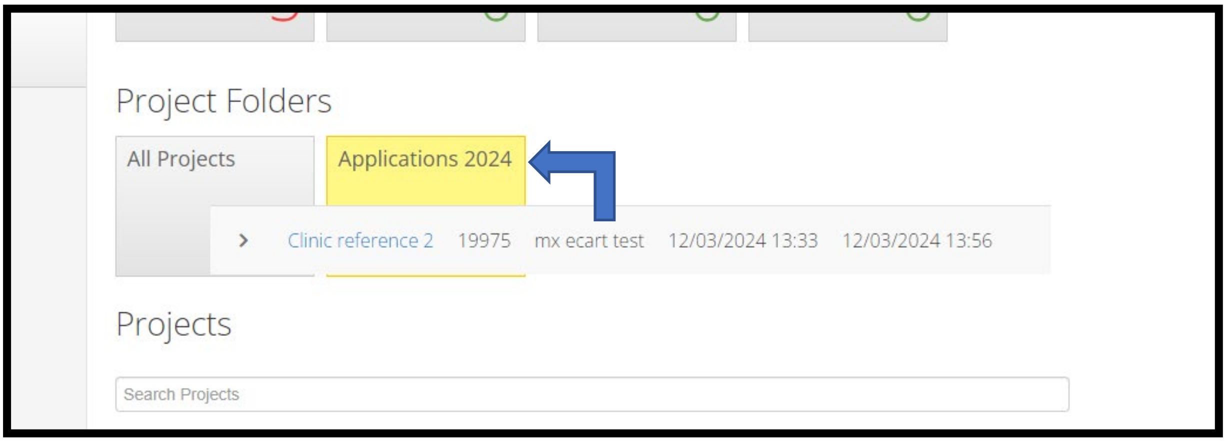
In addition to Create Projects, Delete Project, Duplicate Project and Transfer, there are other options for your Work Area to manage or sort your projects.

Users can create folders by clicking Create Folder to sort their projects into categories or even archive old projects if they wish.

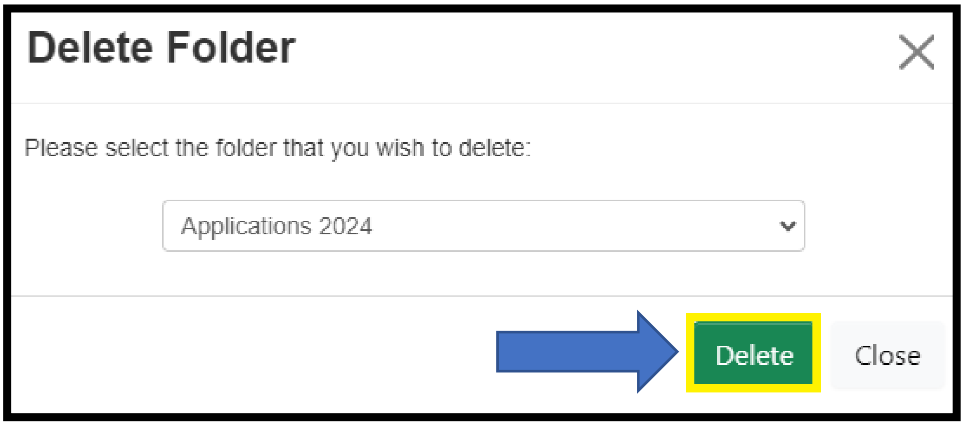


Move Project allows you to move projects into folders, however they may also be ‘dragged and dropped’.





These are user-customisable folders that may be named anything. Delete folder will delete a folder.



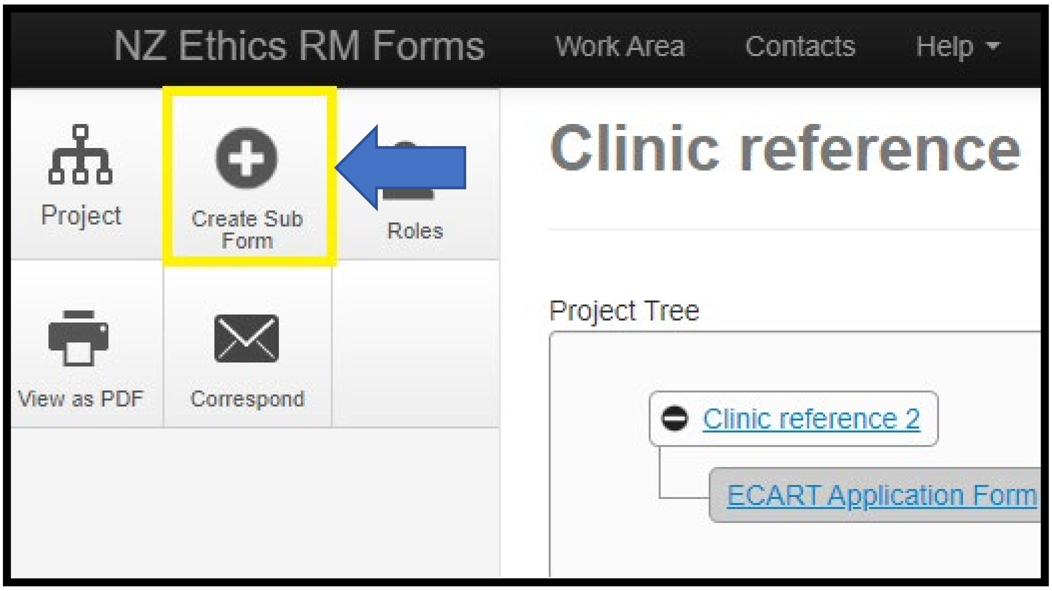
14. Create and submit a Sub Form

What is a Sub form?

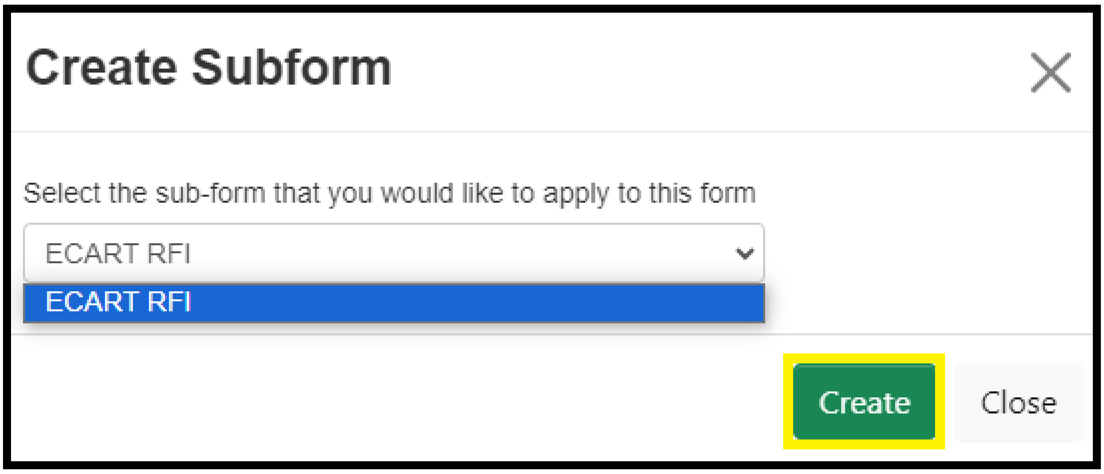
In Ethics RM post approval items are labelled ‘sub forms’ and are attached to their ‘parent form’. The relevant form for ECART applications is call a “Request for Information (RFI)” form.

To start this process, select the application that you would like to add a sub from to. Only the project owner or those with ‘Full Write’ access can create and submit a sub form.

Once in the project, click the “Create Sub Form” button on the left-side of the window.

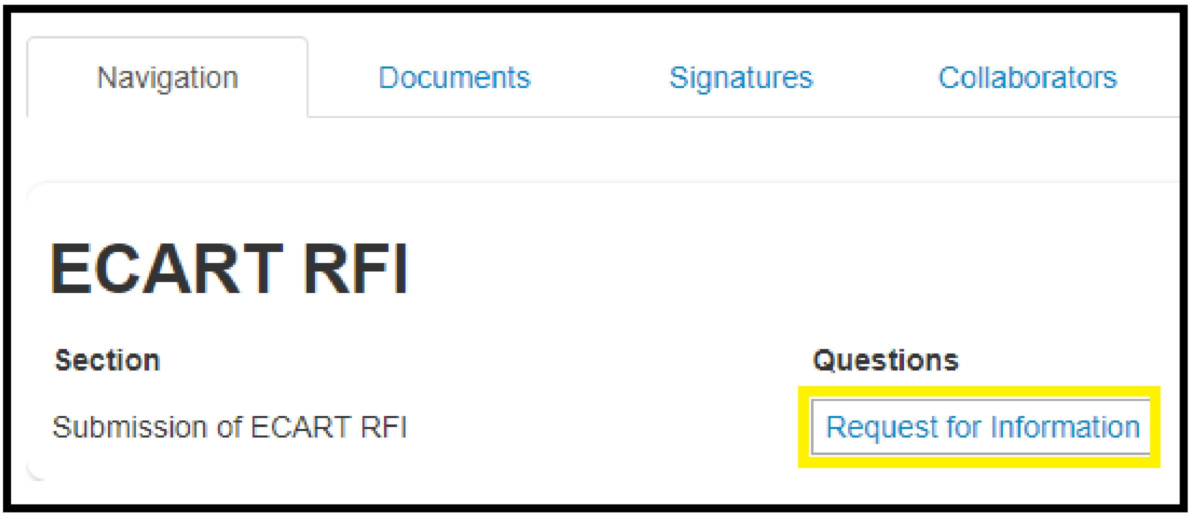


Select which kind of form you require from the drop-down menu and click “Create”.



Your Sub Form will now show up in the project tree under the application. Like applications, Sub Forms can be saved and completed later by clicking the Save button before navigating away.

To fill in the form, click the available question under the Navigation tab. Upload any documents you may have been asked to provide and then press submit as you would with a normal application.



Please note that you cannot use an existing and already reviewed sub form for a new submission and must create a new one every time you wish to provide a submission for Committee review.

15. Contact someone for help/support

ECART queries

The Secretariat cannot provide technical support for all account or login issues but can help with ECART-related queries and any issues with the forms or escalate to technical support if needed. For queries about a specific submission, please use the correspondence function in Ethics RM.

Please provide your project reference when contacting us and allow for 5-7 working days for a response:

Email (general queries about ECART process): ecart@health.govt.nz

Please provide your Project title or project ID when submitting queries. It is helpful to also include screenshots and a full description of your issue, such as what you did to produce an error.

Technical Support

Technical support for Ethics RM is available from Infonetica's IT help desk:

Tel: 0800 634 758 or +64 4 9747675 Assistance is available from **12.01pm to 6pm NZT Mon to Fri** (The Helpdesk is situated in Sydney, Australia).

E-mail: helpdesk@infonetica.net

If the line is busy or if you are calling out of hours please email them at helpdesk@infonetica.net using the Helpdesk Request template so that they can attend to your issue sooner. Otherwise, stay on the line and leave a detailed message after the voicemail.

Please provide your:

- Country – NZ
- Full Name and email address used for login
- Title of project and Project ID (URL and screenshots of the full screen are also useful)
- Short message describing the issue. Please include:
  - full page screen shots
  - copy/paste the URL from the address bar of your browser (eg, https://nz.forms.ethicalreviewmanager.com/Project/Index/234207)
  - email address that you used to login into the system (e.g., Mr Test Applicant (applicant@test.net))
  - Identifying details of your project and details of the issue you are experiencing
- If you wish to locate the owner of a study, please provide:
  - Project title (what you have named the application)
  - ECART reference number.

Please keep your contact details up to date in Personal Details (top right hand corner) so that you can help them help you.