# Ethical Review Manager Application User Guide

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### **Table of Contents**

- o Table of Contents
- Introduction
- Section 1: Ethics RM Account
  - 1.1 Creating an Account
  - 1.2 Forgotten Password
  - Changing personal Details
  - 1.3 Changing Password
- · Section 2: Work Area
  - 0
- 2.1 Work Area Actions Pane.
- 2.2 General
- o 2.3 Folders
- o 2.3 Projects
- SECTION 3: PROJECTS
  - o 3.1 Project Tree
  - o 3.2 Project Action Pane
  - o 3.3 Form Status Table
  - o 3.4 Functions Tab
    - Navigation
    - Documents
    - Signatures
    - Collaborators
    - Submissions
    - Correspondence
    - History
- Section 4: Work Area Action Pane
  - o 4.1 Create a new project
  - o 4.2 Create a folder
  - 4.3 Transfer a project
    - 4.3.1 Cancel a transfer request
    - 4.3.2 Accept a transfer
  - 4.4 Duplicate an existing project
  - 4.5 Move an existing project
- Section 5: Project Action Pane
  - 5.1 Create a sub-form
  - 5.2 Sharing a form through Share Button

- 5.3 Sharing the form through Roles
  - Roles
  - Share
- "Roles" Action not appearing for new owner after transferring forms/sub-forms [For Multi tenant Ethics RM Clients]
- 5.4 Completeness check
- 5.5 Submit
  - Submit with Auto-submission
- o 5.6 Print
- o 5.7 Unlocking a form
- · Section 6: Sub-form Action Pane

0

- 6.1 Duplicate a form
- o 6.2 Transfer a form
- 6.3 Delete a form
- · Section 7: Other Ethics RM Functions
  - 7.1 Contacts
    - Add a Contact
  - 7.2 Signatures
    - Sign a signature
    - Request a signature
    - Accept or Reject a Signature
    - SSO
  - 7.3 Update a project
    - How to update to a newer version
    - How to find the form version?
  - o 7.4 Shared Questions
  - o 7.5 Dynamic Questions
    - Removing/changing a repeatable instance whose response is the source of a Dynamic Question
  - 7.6 View as a Table

### Introduction

Ethics RM is a flexible web-based management system for Ethical Review Boards (ERBs). It improves the ethical review process, saving ERBs' time and effort by automating the application, review and feedback processes. Ethics RM went live in 2013 and has been used across the world to help facilitate the ethical review process.

If you are new to Ethics RM, then one of the things that you need to do is obtain your own Ethics RM account.

Obtaining an Ethics RM applicant account is a simple process: you will need a valid email address and access to the website, where you can sign-up from login.

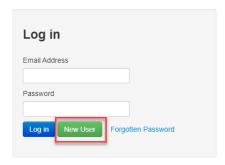
You should always use your own account to access Ethics RM.

Organisations with Single Sign On (SSO) set-up will create an Ethics RM account on login using their organisation's login details.

# Section 1: Ethics RM Account

# 1.1 Creating an Account

- 1. Navigate to the Ethics RM site.
- 2. Click on New User.
- 3. Fill in the relevant information and agree to the Terms and Conditions.
- 4. Click Register and an activation email will be sent to the entered address.
- 5. Access email and click the activation link provided and the account will now be activated.
- 6. Click Log in.
- 7. Log in with your email address and password.



# 1.2 Forgotten Password

- 1. When logging in as an applicant, if the password entered is incorrect an error message will appear.
- 2. Click on Forgotten Password.



3. Enter the email address of the account you wish to be signed into.



- 4. Click Return to Login.
- 5. You will receive an email that contains a link that will allow you to change your password. The email may sometimes be in junk/spam or may be blocked by your Institution.
- 6. Enter your new password in the box provided and confirm it in the other, both passwords must match.
- 7. Click Reset Password.

8. You will then be shown a message confirming the change of your password.

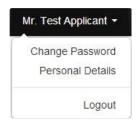
Your password has successfully been reset, please click here to return to login page.

Your password has successfully been reset, please click here to return to login page.

Reminder: the email could be in the junk/spam folder or blocked by your Institution.

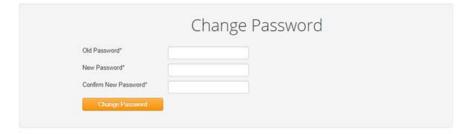
# Changing personal Details

- 1. Sign in as an applicant, click on name located top right of browser.
- 2. Click Personal Details.



# 1.3 Changing Password

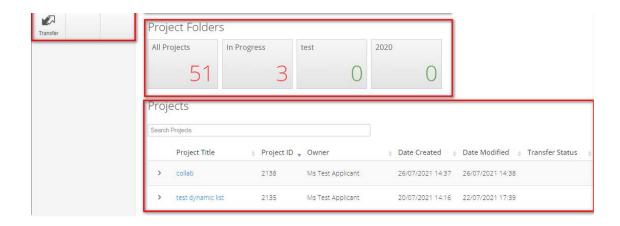
- 1. Signed in as an applicant, click on name located on top-right of browser.
- 2. Click Change Password.
- 3. Enter old and new password.
- 4. Click Change Password.



# Section 2: Work Area

The Work Area is on the Ethics RM home page. The left side of the screen displays the Actions pane with function buttons below. The right side of the screen displays a General Section, Folders Section and an overview of projects in the user's Ethics RM account.





### 2.1 Work Area Actions Pane.



Create a new project.



Delete a project (only possible if the main form has not been submitted via Ethics RM).



Create a bespoke folder for storage of projects.



Delete a folder (only possible if the folder is empty).



Permanently transfer a project to a colleague.





Duplicate an existing project.



Move a project to another folder or to main page.

### 2.2 General

There are four tiles at the top of the Work Area. If the tile displays a **red** number, it may contain items that require attention.



**Notifications -** Contains messages that are sent to the user from the Research Office and other research team members.

• Also contains messages automatically generated by Ethics RM e.g. form updates.

**Signature** - Contains requests from colleagues to digitally sign an application i.e. a request for an electronic signature.

Transfers - Contains requests to transfer a project to another Ethics RM user.

**Shared** - Contains information about forms and the level of access another Ethics RM user has shared with you.

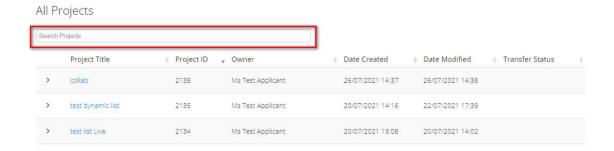
### 2.3 Folders

All applications are listed together in the Work Area home page. Folders can be created to organise applications accordingly.

# Project Folders

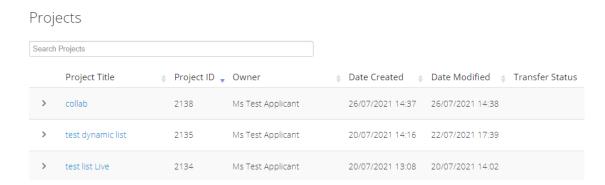


If there are 1 or more custom folders an "All Projects" folder will appear. This will allow you to search for a particular project.

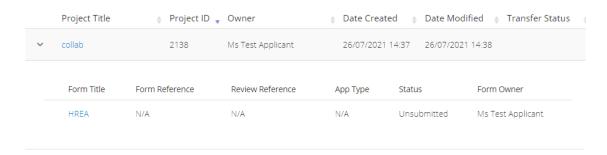


# 2.3 Projects

Projects in the user's Ethics RM account are listed under Projects. To access a project, begin by typing the project's title in the 'Search Projects' text box. Note, this search will not display results that have been moved to folders.



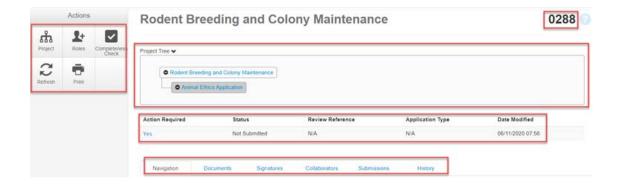
The ">" arrow next to the project Title will expand the project to display the associated forms.



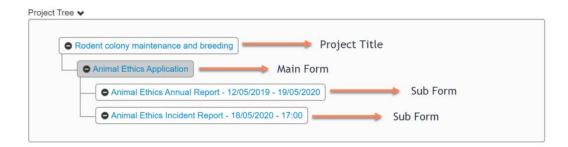
It will display the form's details including status and owner.

# **SECTION 3: PROJECTS**

Upon clicking on a project from the work area, you will be presented with the project page. The left side of the screen displays the **Actions pane** with function buttons below. The right-hand side displays the **Project tree**, **Form status table** and **Tab functions**. The **project ID** is displayed on the top right-hand



# 3.1 Project Tree



- Ethics RM is based on forms. The applicant creates a project and a main form simultaneously
- From the main form, the applicant can create sub-forms e.g. Progress Reports, Amendments, Annual Reports.
- From some sub-forms, further sub-forms can be created e.g. Site Progress Report, Complaints Report and Site Notification Form.

# 3.2 Project Action Pane

Note the below may not all be on display. What is displayed is dependent on what the Ethics RM admin has made available.



Go to the Project overview.



Create a sub-form from the main form e.g. Amendment, Progress Report, Final Report, Suspected Breach Report.



Enable collaborators to view, edit and manage the form.



Enable collaborators to view, edit and manage the form.



Identify mandatory questions within the form that require information to be entered.



Submit the application to the reviewing organisation.



Generate a PDF of the form.



Communicate directly with the Research Office selected as the reviewing organisation, within the form, only after the form has been submitted.



### 3.3 Form Status Table

The form status displays the current activity and status of the form.

- 'Action Required' column: indicates if any actions are required by the user Yes or No. When the
   'Action required' displays Yes, the text is blue, and the user can click the text to run a 'completeness check'. This lists the actions required before the form can be submitted.
- Status: indicates the status or stage of the form, for example: Not submitted, Submitted, Validated, Information Requested and Approved.
- Review Reference: remains as N/A until the form is submitted and is then populated with a unique identification code and it is one of the ways to identify a submitted form, along with project ID.
- Application Type: identifies the type of application/form submitted for example Human Ethics, Animal Ethics, Quality Assurance or Bio Safety.
- Date Modified: displays the most recent date the form was modified.



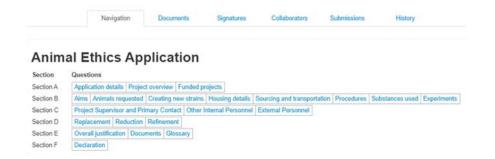
### 3.4 Functions Tab

There are seven tabs that cover specific aspects of the application and its submission process.



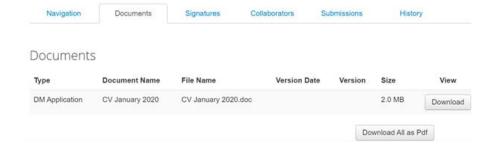
### **Navigation**

- The Navigation tab displays the sections and associated questions within the form. Sections will become accessible or inaccessible depending on the information relative to the application.
- Questions are hyperlinked (in blue) for quick navigation to the relevant section within the form.



### **Documents**

The Documents tab displays current supporting documents that have been uploaded into the form.
 The details displayed indicate the document type, name, file name, version date and number.
 Documents are not uploaded through this tab.



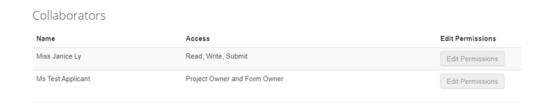
### **Signatures**

- Displays a history of all digital signatures that have been signed on the form and shows all signature requests. Signatures are not signed under this tab.
- To sign a form, use the Navigation tab to access the relevant section for signature requests.



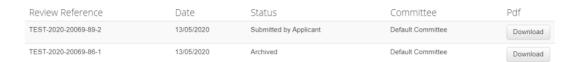
### **Collaborators**

- Displays all members of the research team who have access to the application/form.
- To view a collaborator's Ethics RM email account, click on the collaborator's name and the email account will be displayed.
- The form owner can edit the permissions for each collaborator only if the access level is assigned through the **Share** action.



### **Submissions**

- Displays the Review Reference, the current status of the application/form and the Committee that will review the application.
- Under PDF you may select Download to print application/form if required.
- Each time the form is resubmitted, a new review reference is provided.



### Correspondence

- Displays a record of the communication between the user and the reviewing organisation's research office.
- Use the Correspond button under the Actions pane to write and send a message to the Research Office.
- Correspondence may not always display as it is dependent on whether your organisation has turned this on



### **History**

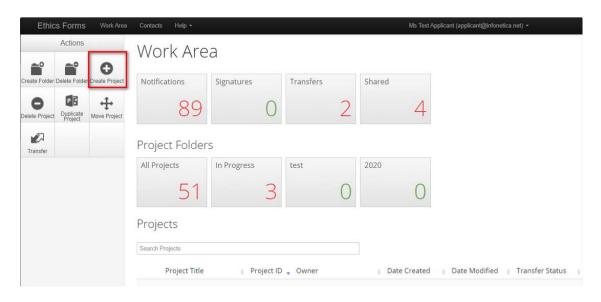
- Displays an audit trail of the application/form.
- The user actions are recorded including actions from the Research Office once an application/form has been submitted.
- Attachments (application/form as PDF) can be downloaded and viewed if an action includes submitting a form.



# Section 4: Work Area Action Pane

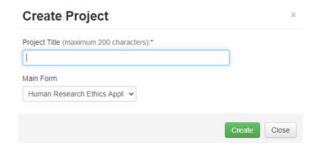
# 4.1 Create a new project

Select Create Project button under the Actions pane in the Work Area.



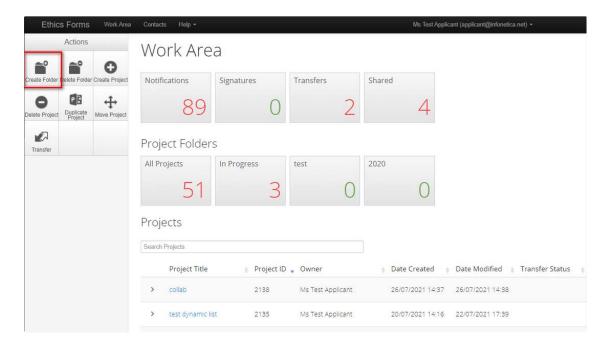


Enter the Project Title and select a main form from the drop-down list and click create.



### 4.2 Create a folder

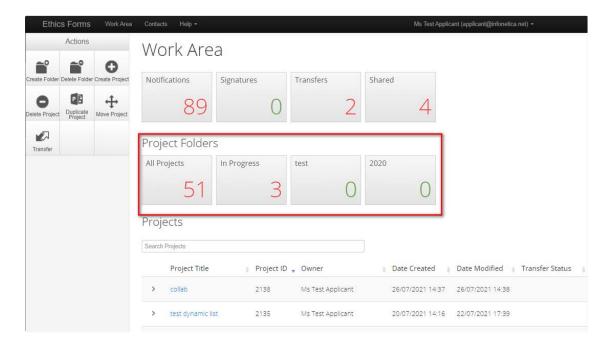
Select Create Folder button under the Actions Pane in Work Area.



Enter a Folder Title and click create.



A new Folder tile (In Progress) is displayed in the Work Area under Folders.



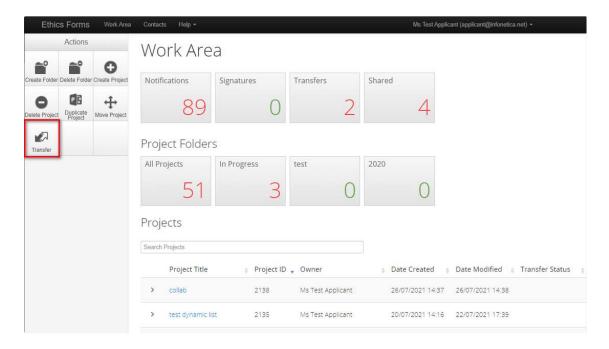
Applications listed under Projects can be moved to the new folder using 'drag and drop'.

Select the Folder tile to display the list of projects moved to the Folder.

# 4.3 Transfer a project

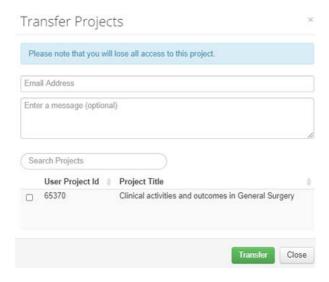
The project owner can use the Transfer function to permanently transfer a project to <u>another Ethics RM user</u>. This may be when a Sponsor creates an application then transfers it permanently to the Coordinating Principal Investigator (CPI) or, when the project owner intends to leave the project and transfers project responsibilities to another collaborator in the research team.

Select the transfer button under the actions pane in the 'Work Area'.



- Transfer Projects text box is displayed noting loss of future access to the project.
- The project owner enters the ensuing project owner's Ethics RM email address.

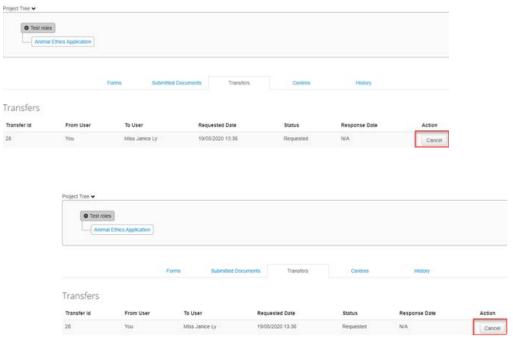
- Enter a message to the new project owner (optional).
- Select the correct project from the list and select **Transfer** button.



All forms are locked pending the transfer. The new project owner will receive an email notification regarding the transfer of the project

### 4.3.1 Cancel a transfer request

The project owner can cancel the transfer request if the request has not been accepted by the new project owner. In the Project Overview page, under the Transfers tab, select the **Cancel** button.



To get to the Project Overview page, select on the **Project** button under the Actions pane or click on the Project Title in the project tree.





A message indicating the transfer request has been successfully cancelled will be displayed.

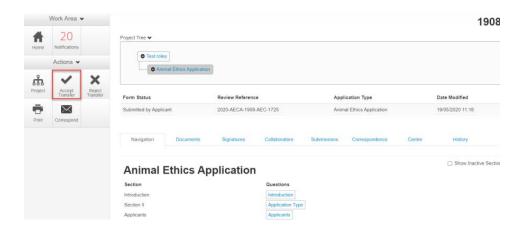
### 4.3.2 Accept a transfer

The new project owner will receive an email notification to log in to their Ethics RM account. In the Work Area, select the **Transfers** tile.

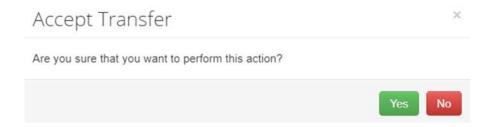
A list of all transfers will be displayed. In the relevant message line, select **View Project** to open the project as read only



To accept the transfer, select the **Accept Transfer** button from the 'Actions' pane.



An Accept Transfer text box is displayed. Select **Yes** to accept the transfer.



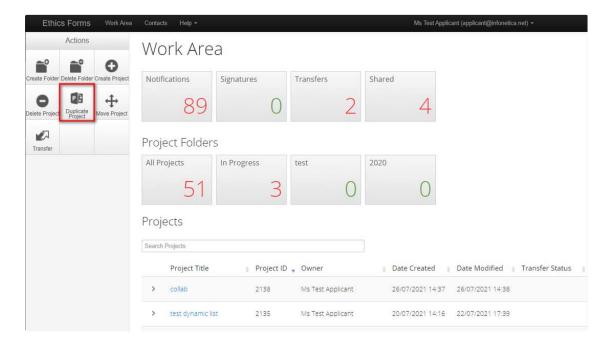
Ownership of the project is transferred including all sub-forms. The new owner can access the project from their Work Area and assign other research members access to the project. To reject a transfer, select the **Reject Transfer** button.

Once a project transfer has been accepted, it will be in the new owner's list of projects.

# 4.4 Duplicate an existing project

In Ethics RM, an existing project can be duplicated regardless of whether the project has been submitted or not. Sub-forms can also be duplicated in this process.

From the Work Area select **Duplicate** Project.



- A Duplicate Project textbox will be displayed.
- Select the project to be duplicated.
- Enter a new title for the project and delete the previous project's ID number.
- · Select Include sub-forms if sub-forms are also to be duplicated
- Select **Duplicate**



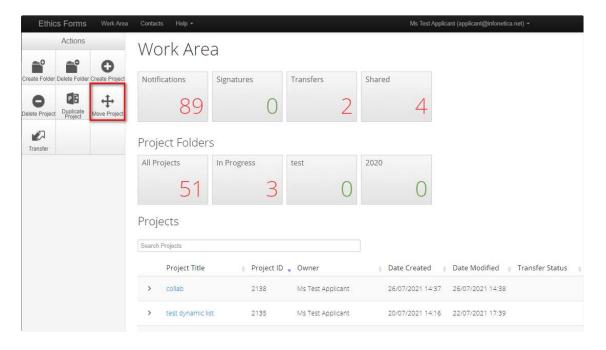
The duplicate project with the new title will be displayed under Project Title.



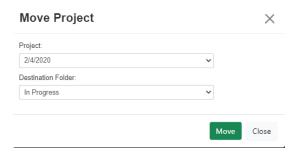


# 4.5 Move an existing project

An existing project can be moved from one folder to another.



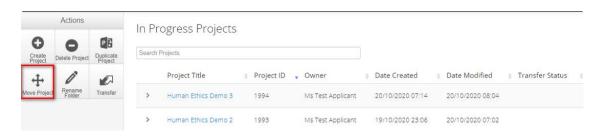
Select Move Project then fill in the Move Project screen.



The Project Drop down list will list all Projects in all Folders.

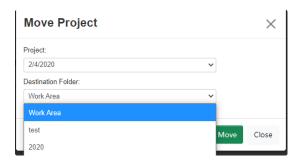
The Destination Folder drop down list will list all available folders.

Once in a particular Folder the 'Move Folder' action is still available.





However when you select Move Project it will include in the list, the Work Area.

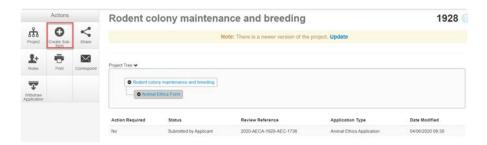


This will allow you to move the Project out of the Folder and into the Work Area.

# Section 5: Project Action Pane

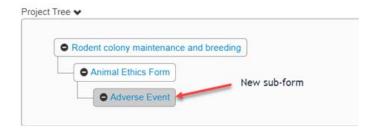
### 5.1 Create a sub-form

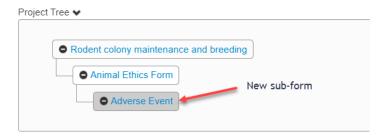
Select the Create sub-form button under the project's 'Actions' pane.



A 'Create Sub-form' box will be displayed. Select the sub-form you would like to create and then select the **create** button.

The Project Tree will display the newly created sub-form under the main form.



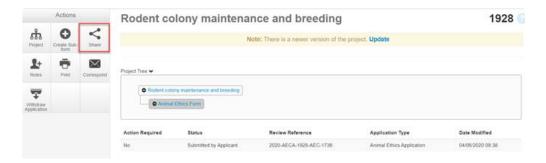


Occasionally, you may not be able to create a sub-form or view the 'create sub-form' button if your main form or an existing sub-form has a certain status. The statuses that prevent creation are configured by your organisation.

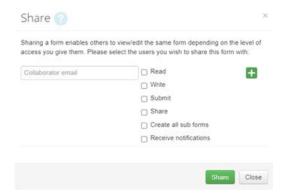
# 5.2 Sharing a form through Share Button

In Ethics RM, a project owner or form owner can make the project or form accessible to other researchers using the **Share** function.

Select the **Share** button under the actions pane on a project page.



A share text box is displayed, enabling the researcher to add a collaborator's email and a level of access including: 'read', 'write', 'share', 'submit', 'create all sub-forms' and 'receive notifications'. Select the **Share** button.



Select the **plus** button on the top right-hand corner to add more than one collaborator. Select the **minus** button to delete a collaborator.

Once the collaborator has been shared, they will appear under the collaborator's tab.

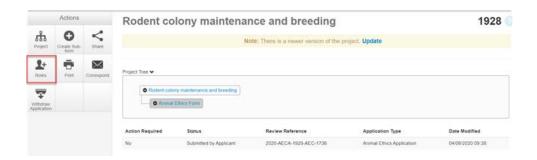




# 5.3 Sharing the form through Roles

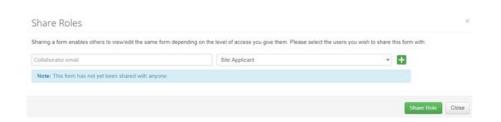
In Ethics RM, a project owner or form owner can make the project or form accessible to other researchers using the **Roles** function.

Select the Roles button under the Actions pane.



Enter the collaborator's email address and select the Role Type.

Select Share Role button.



The benefits of using **roles** as opposed to **share** are that the researcher the form has been shared with will be able to <u>see up the project tree</u>.

If the collaborator does not have an Ethics RM account

A message will be displayed when a collaborator's email does not exist in Ethics RM. Select the **Invite** button to invite the collaborator to create an Ethics RM account.





This raises a green bar across the screen advising the collaborator has been successfully invited.



The collaborator will receive an email notification with a link to Ethics RM to create an account. The collaborator should also notify the project owner when their Ethics RM account has been activated.

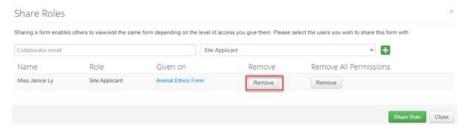
The project owner will need to <u>repeat the steps</u> to assign the collaborator access to the form.

### **Editing Roles and Share Access**

A collaborator's level of access to a form can be changed in two ways depending on whether 'Roles' or 'Share' has been used to assign access.

### Roles

- Highlight the relevant form in the Project Tree and select the Roles button under the 'Actions' pane.
- A 'Share Roles' textbox will be displayed showing the form's level of access that has been assigned to the collaborator.
- · Select Remove.



The 'Share Roles' page remains presented to allow the level of access to be modified.

- Enter the collaborator's Ethics RM email address and new level of access e.g. read, create sub-forms.
- Select Share Role.
- The collaborator will receive an email notification informing them of the change in their access level.

### Share

- Highlight the relevant form in the Project Tree and move to the Collaborators tab.
- Select the **Edit Permissions** button to modify the collaborator's access level.

### Collaborators



- An 'Edit Permissions' textbox will be displayed. Edit the permissions and select Save.
- The collaborator will receive an email or message in the Notifications tile (under the Work Area) informing them of the change in their access level.



# "Roles" Action not appearing for new owner after transferring forms/subforms [For Multi tenant Ethics RM Clients]

Transferring the ownership of forms and sub-forms to users in different jurisdictions is the same as how you would transfer a form to someone in your own jurisdiction. But there are some differences you should be aware of.

Just transferring the form alone will not provide the new owner with access, for themselves, to grant access to additional users to the form using "Roles".

The ability to grant access via the "Roles" action will not be available to them automatically. For the new owner to have access to this function the original project owner will need to provide access to the form using the Roles from their own Ethics RM account before transferring ownership. The role assigned to the new user MUST include the share option.

Or otherwise, the new form owner can assign their own permissions using the "Share" action.

# 5.4 Completeness check

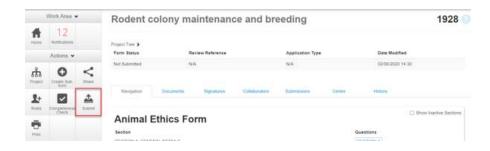
The 'completeness checker' enables the researcher to determine which form question have not been completed.

- Select the **Completeness check** button under the project Action pane.
- Selecting the **blue links** will take the user to that question of the form.

# Incomplete: Please complete the following questions - Which committee will the application be submitted to? - 12 Please enter the contact details for the Principal Investigator at this University - 1.3() Proposed commencement date: - Laboratory - 1.5 Please attach a list all SWI procedures that will be used in this protocol - Please attach permits - Valid From - Valid From - Valid To - 2.9(iii) Do any of the features of the proposal raise special ethical considerations? - 2.9(v) Do you expect any animals to die during your experiment? - 3.3.4(ii) A clinical record sheet that is tailored to the requirements of this proposal needs to be produced and attached. - 3.3.5 What post-operative care will the animals require? - 4.1 List all personnel involved in the project - 5.2 I am satisfied that the applicant has the appropriate qualifications and experience to perform the proposed experiment and that the scientific value of the project justifies the potential effects on the welfare of the animals.

### 5.5 Submit

Navigate to the Actions pane and select the **Submit** button.



The system automatically performs a completeness check to highlight any incomplete sections.



If complete, the form is ready to be submitted. Select the **Submit** button.



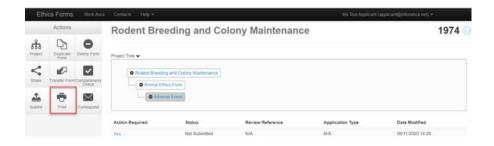
### **Submit with Auto-submission**

If 'auto-submissions' has been turned by your organisation, there will be <u>no submit button</u> in the 'Actions' panel. The form will be automatically submitted when signatures are signed.

Submission will not be initiated immediately, but the form will be submitted within 10 minutes.

### 5.6 Print

The **print** button can be utilised to generate a PDF of the selected form to be saved to your local drive.



Checking **With Tabular Summaries** means the generated PDF will display responses where applicable as a Table. Select **Print**.



# 5.7 Unlocking a form

Upon signing a signature, the form will immediately be locked. Unlocking a form will enable the user to continue to make edits.

Select the Unlock button.



An Unlock Form text box will be displayed, warning the user that unlocking the form will <u>invalidate any signatures</u>. This will require signatures to be re-signed. Select **Confirm**.



A banner will display 'form unlocked'.

# Section 6: Sub-form Action Pane

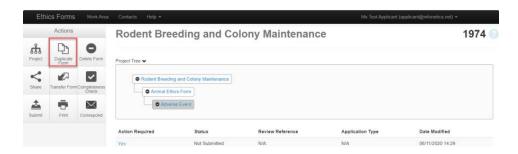
On a sub-form level, the below actions will be displayed.

# 6.1 Duplicate a form

Sub-forms can be duplicated using a similar 'duplicate' function.

The duplicate function will copy all answers in the form but not copy documents, signatures and permissions assigned to the original sub-form.

• In the Project Tree highlight the sub-form to be duplicated



- · A 'Duplicate Form' textbox will be displayed if settings allow for a form to be duplicated
- Select number of duplicates required e.g. 2
- Select Duplicate



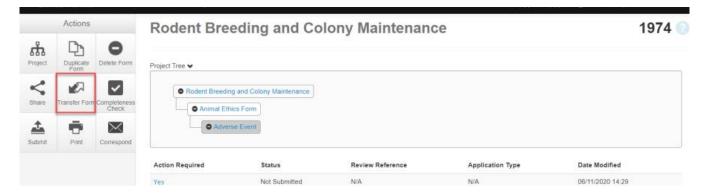


The duplicated sub-forms will be displayed in the Project Tree.

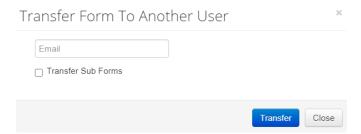
### 6.2 Transfer a form

A form owner can transfer sub-forms. For the form transfer to be successful the form must first be shared with the intended new owner either via **roles or share** button.

- Select the sub-form you would like to transfer on the project tree.
- Select **Transfer Form** button under the Actions pane.



- A Transfer Form To Another User text box will be displayed.
- Select the Transfer Sub-Forms checkbox to include other sub-forms that are associated with the form e.g. a Site Progress Report.
- · Select Transfer.

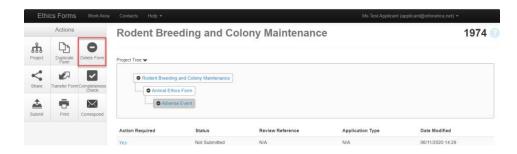


- A Transfer successful message will be displayed at the top of the screen.
- The collaborator will receive an email notification informing them of the transfer with a link to Ethics RM and becomes the new form owner including the owner of any associated sub-forms.
- The new form owner is shown under the **Collaborators** tab.

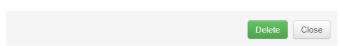
# 6.3 Delete a form

The applicant can delete a sub-form if it has been created unnecessarily but can only be performed if the form <u>has not been submitted</u>.

In the Project Tree, highlight the sub-form which needs to be deleted. Select the **Delete Form** button under the 'Actions' pane.



A Delete Form text box is displayed. Select **Delete** to delete the form.



If the form has been signed by the signatory, open the form and select the 'Unlock' button under the Actions pane.

# **Section 7: Other Ethics RM Functions**

The Contacts area can be used to 'save' and 'edit' contact details for project team members. Details saved in Contacts can be used to populate all Ethics RM forms.

### 7.1 Contacts

### **Add a Contact**

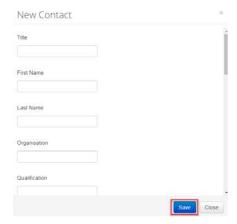
• Select Contacts above the Work Area.



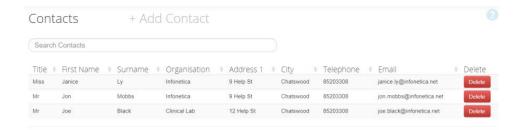
• Select + Add Contact



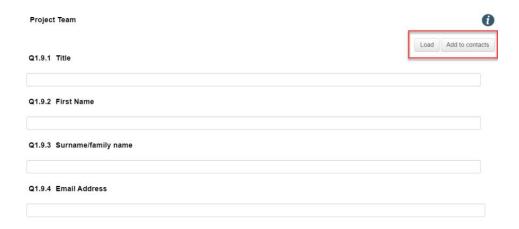
• A New Contact textbox will be displayed to enter the new details. Select **Save** button



• New contact details will be displayed under Contacts



- · Contacts can also be added when completing a form by selecting the Add to Contacts Button.
- · Selecting Load, populates contact details from your Contacts List.



# 7.2 Signatures

### Sign a signature

To sign a signature, select the **Sign** button.



The 'completeness checker' then automatically runs and displays results to highlight any incomplete questions. Each incomplete item will be displayed as a link to the relevant section. Enter your Ethics RM details and select **Sign**.



A banner will display 'signature successful' and the message under the signature will display indicating the form has been signed.



### Request a signature

To request an electronic signature from another user, for example the Head of Department or Facilities Manager, select **Request Signature** button.

- The 'completeness checker' automatically runs to highlight any mandatory incomplete sections. Each incomplete item will be displayed as a link to the relevant section.
- When all required sections of the form have been completed select Request Signature.



Enter the signatory's Ethics RM email address and message and select Request.



The requested signatory will receive an email notification with the signature request, a message and a link to the Ethics RM Log in/Signatures page. If the signatory does not exist in Ethics RM, there will be an **Invite** button to invite user to join Ethics RM.

### Accept or Reject a Signature

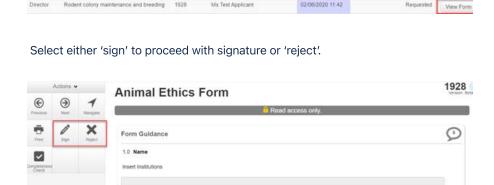
If a user has been requested for a signature, they may 'accept' or 'reject' a signature.

Select on the **Signature** tile in the Work Area Page.

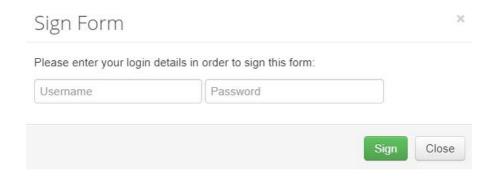
# Work Area



If a signature has not been 'accepted' or 'rejected', the status will be 'requested'. Click **View Form** on the project that you would like to sign.



A 'sign form' textbox is displayed. The signatory enters their Ethics RM login details to sign the form and selects **Sign**.



A banner displays 'form signed successfully', and the applicant receives an email notification indicating the signature request has been accepted by the signatory i.e. the form has been signed.

Upon selecting the **Reject** button, a Reject Signature text box will be displayed. The signatory enters their Ethics RM login details. A reason can be entered but is not mandatory.



### SSO

If your Institution uses Single Sign On (SSO), you will <u>not</u> need to enter in your Username and Password. Clicking 'sign' will sign the form without any further steps.

Following the acceptance or rejection of signature, the status will change from 'Requested' to 'Signed' or 'Rejected' on the list in the Signature Tile.



# 7.3 Update a project

A notification to update a project will appear when there has been a <u>modification</u> to a <u>form</u> or a <u>process</u> within Ethics RM. This action ensures access to the <u>most recent version</u> of forms used in Ethics RM.

- Only the project owner may update a project.
- Approved forms retain the version they were approved at.
- Forms and sub-forms that have been submitted or under review will also be updated.
- Forms with electronic signatures applied but not submitted, should be updated <u>after</u> submission, otherwise updating will <u>invalidate</u> electronic signatures.

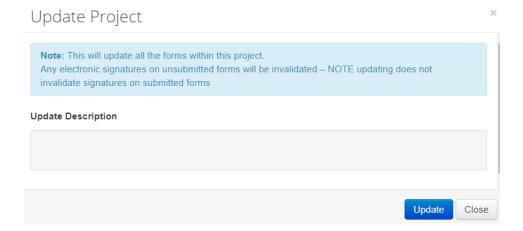
### How to update to a newer version

• Print and save a copy of any unsubmitted forms before the project is updated to ensure no data is lost by using the print action button.



• The Update prompt is viewed by the project owner at the top of the form. The project owner clicks on the 'Update' link.

• A pop-up message displays information about electronic signatures on unsubmitted forms which will be invalidated if a project is updated. Select the **Update** button to update the project.



- A Message box will be displayed informing the project owner of the update.
- If the completion of a form is in progress, select the Completeness Check button under the Actions
  pane to check if additional data entry is required as the new version may introduce additional
  questions into the form.
- An Update prompt is also seen by collaborators and form owners should advise the project owner of
  any need to delay the update. For example, if the form owner is working on a form with unsubmitted
  electronic signatures.

Note: There is a newer version of the project. (Please contact the project owner to update this form).

### How to find the form version?

- The form version appears at the top right-hand corner of the screen when the form is open.
- The most recent date a form has been edited is displayed under Date Modified below the Project Tree.

### 7.4 Shared Questions

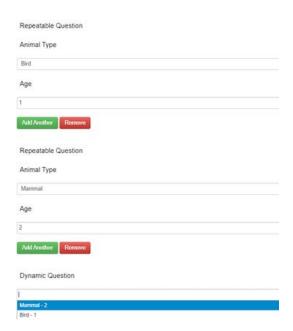
When signed in as an applicant, while completing a sub-form you may encounter a 'locked question' or a question that already contains an answer with a **red** 'shared icon' on the right-hand side of question.



This is because the question is shared with another form which has been already been completed or is locked. On the instance that it is unlocked you will be informed that any changes made to this question will affect the corresponding form.

### 7.5 Dynamic Questions

Dynamic Questions is a new feature that enables the applicant to reference and reuse 'repeatable question' responses. This feature is particularly useful when researchers have to re-enter the same information multiple times. The feature will also concatenate repeatable responses from the source question. When filling out an application form on the Forms side, a user will answer the repeatable question creating as many instances as required. When selecting from the Dynamic question, all selected options will appear.



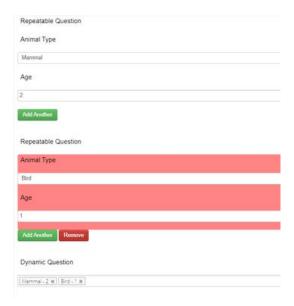
This is what the dynamic question will look like, once the instances are selected on the Form side and Reviewer side.



# Removing/changing a repeatable instance whose response is the source of a Dynamic Question

Removing or changing a repeatable instance that is the source to a Dynamic Question will result in the answer to the Dynamic Question being removed or changed to reflect the new answer. All other instances in the selection should remain unchanged.

For example, If Bird-1 Source repeatable question is removed, you will be left with Mammal-2 as the only dynamic question instance.



As seen below, Bird-1 is now removed and only Mammal-2 remains when the second repeatable question is removed.



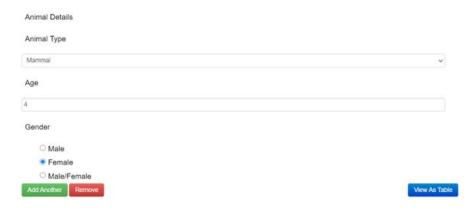
When changing the source question answer for example from Mammal Age 2 to Age 1, the new answer will show Mammal – 1 in the dynamic question.

### 7.6 View as a Table

This feature allows for applicants and reviewers to view selected fields in a Repeatable Question Group (RQG) as a Table.

The aim of this feature is to help Forms users and Reviewers more easily read information in repeatable questions both in the form view and in the print.

Select **View as Table** button after any configured RQG. After the question instances have been created, filled out and saved, the button will become available.



### This is the table view. Select **View as a form** to revert back to form view.

Animal Type	Age	Gender
Bird	2	Female
Mammal	4	Female