ERM Biosafety User Guide For Researchers

Contents

1   Logging in

- Go to https://ethicsapps.swin.edu.au/
- Click on Log in on the top right hand corner
- Swinburne (Ethics Review Manager) ERM is fully integrated into the Swinburne Single Sign on. All researchers with an @swin.edu.au or @swin.edu.my will be able to access the application portal.
- Use your Swinburne account (Swinburne email address) as the username (or pick your existing account)
- Use your email password for the password- click sign in.
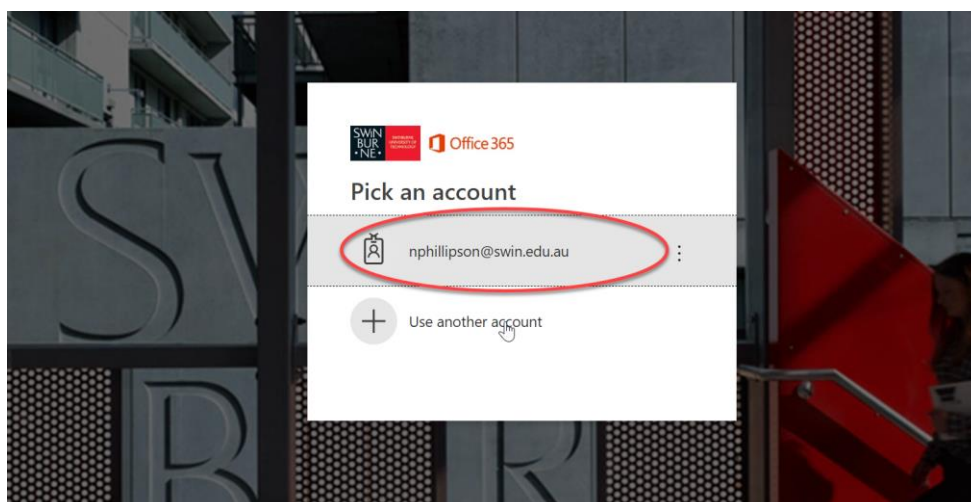- If you have any issues logging on email resethics@swin.edu.au

- If you have signed in before your name will appear in the top right hand side indicating you are logged in. Click on home to take you to your work area. If you wish to log in as a different user Log out and you can then log back in again using a different username.
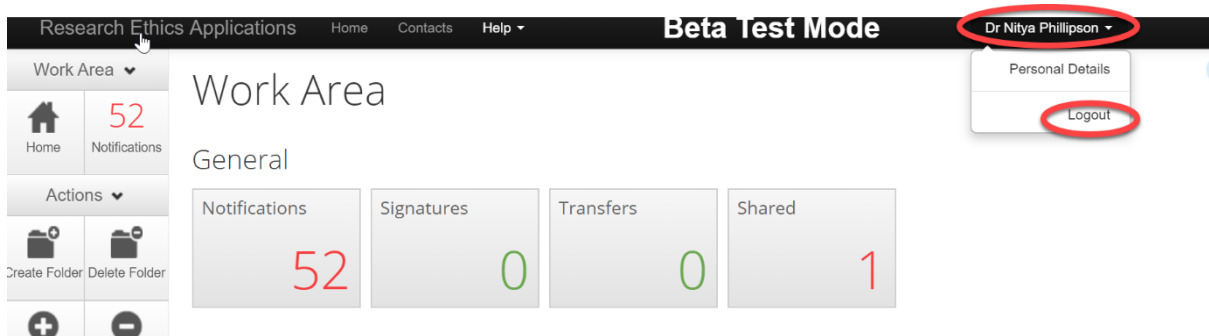
1.1 How to log in as an external applicant (I don't have a Swinburne email address)?

- If you do not have a Swinburne email address contact the Research Ethics & Integrity team on resethics@swin.edu.au or 03 9214 3845 or 03 9214 8145 and provide the following information
  - o The email address you wish to use to access the ERM
  - o Information regarding which Swinburne researchers and project you are collaborating with
  - o A brief summary about your research and Swinburne's involvement.
- We will then create an account for you and provide you with a username and password.

# 2 Selecting the right application for you

2.1 Different applications available:

- There are also different types of Human and animal ethics applications available on ERM. Please see the links for more information on how to submit a human ethics application or animal ethics application http://www.swinburne.edu.au/research/ethics/swinburne-online-ethics-review-management-system/
- These options are found when you select 'Create project' icon in the Actions Panel on the left-hand side (LHS) of the landing page.

- The drop-down list for Main Form lists these as options

2.1.1 Biosafety

- Biosafety Clearance Application: For research requiring biosafety clearance as you are using biohazardous materials (e.g. venoms or blood products) and/or genetically modified organisms (e.g. genetically modified cell lines, bacteria, plants or other organisms).
- These applications will be reviewed by the Swinburne Biosafety Committee (SBC) and are called SBC applications in this document.
- If you have any questions about whether you should be using this form, please contact resethics@swin.edu.au
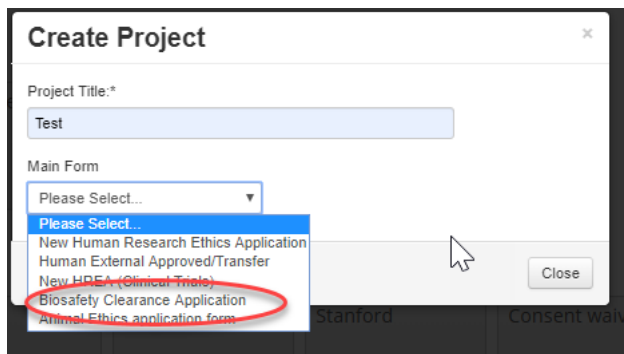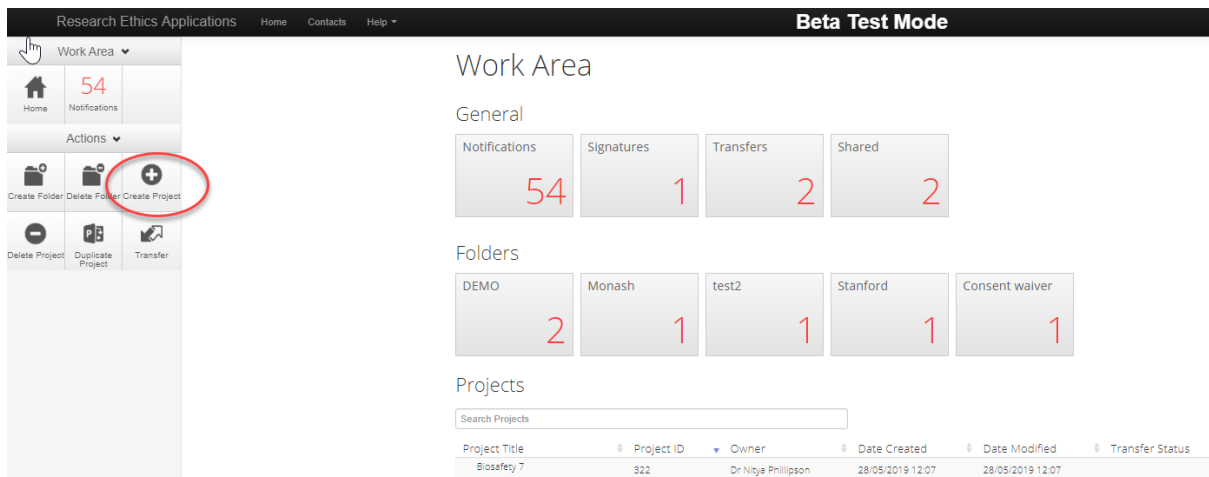
3 How to complete a Biosafety application

3.1 Drafting your application

- Once you have created your application you will be taken to this navigation page
- We strongly recommend you commence at the Start section as this will take you through a series of checklist that will create and remove sections depending on how you answer these
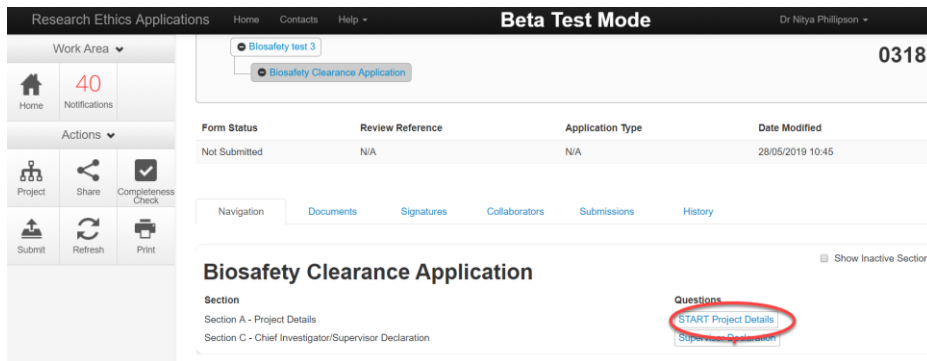
- Navigate through the form by clicking Next or Previous
- You can see overall structure of the form by clicking on navigate icon and then click on the relevant sections of the form to take you to that section
- You can conduct a completeness check at any time by selecting the completeness check button in action tab on the LHS and go directly to any incomplete section by clicking on the sections highlighted as incomplete.
- Please note that only the Chief Investigator can submit an ethics application. Please see section 6 for more information.
- Please save your application frequently to avoid losing any work. To do this click on the Save button on the LHS actions tab.


3.2   Need help with a question

- To see help sections click on the *i* icon next to the question
- A help text will pop up in a window, if there are hyperlinks these will open in a new tab when you click on them.
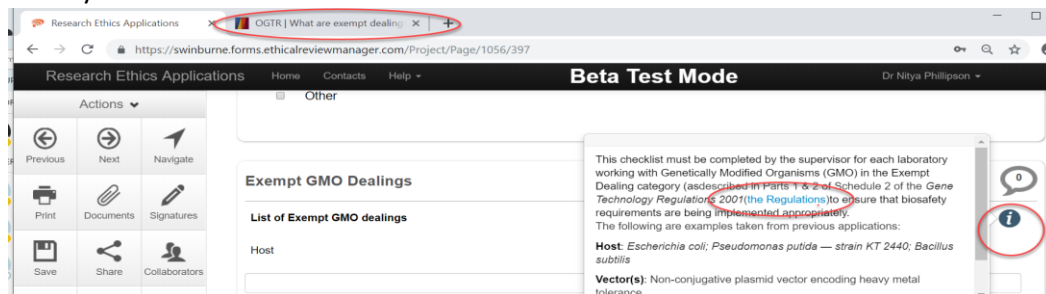

3.3   Attaching relevant documents

- You may be prompted at certain points to upload a document to do this click upload documents
- Click browse to select the file on your computer you wish to upload, enter a version date and number to ensure document control
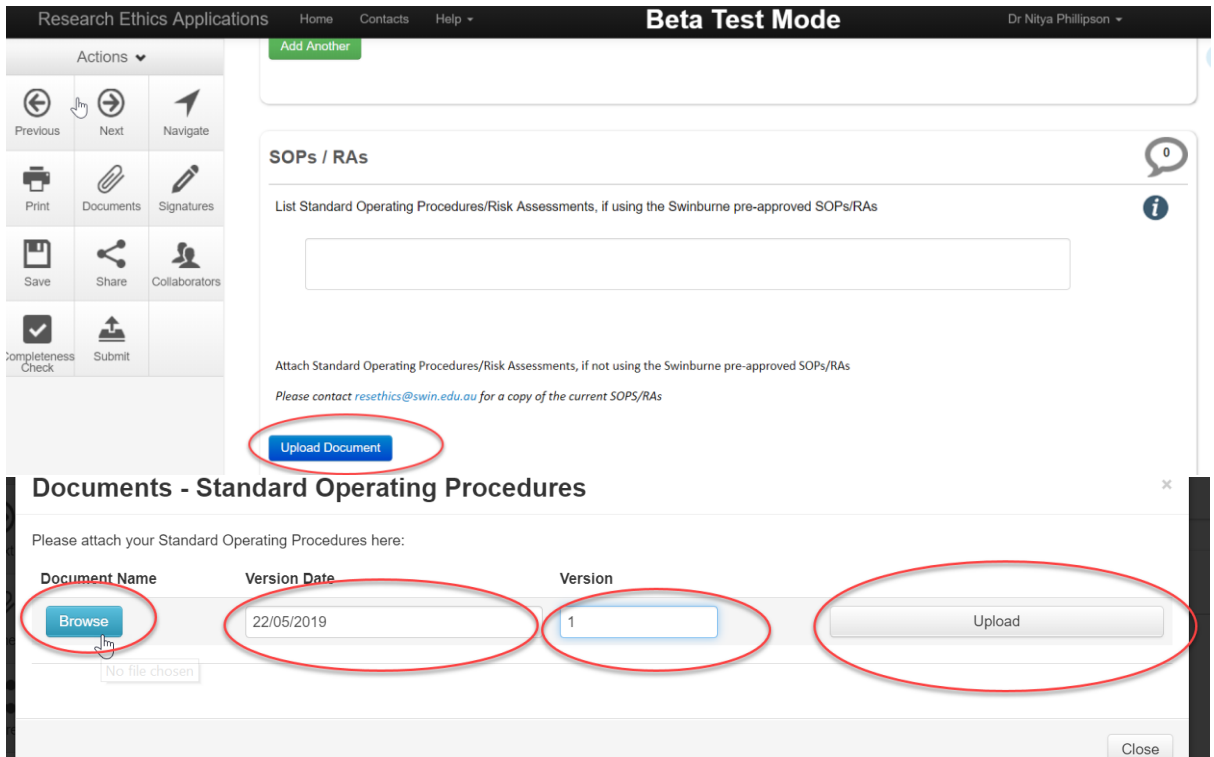
- You can review all documents uploaded to the application using the Document button on the LHS actions tab
- These can be downloaded separately or all together
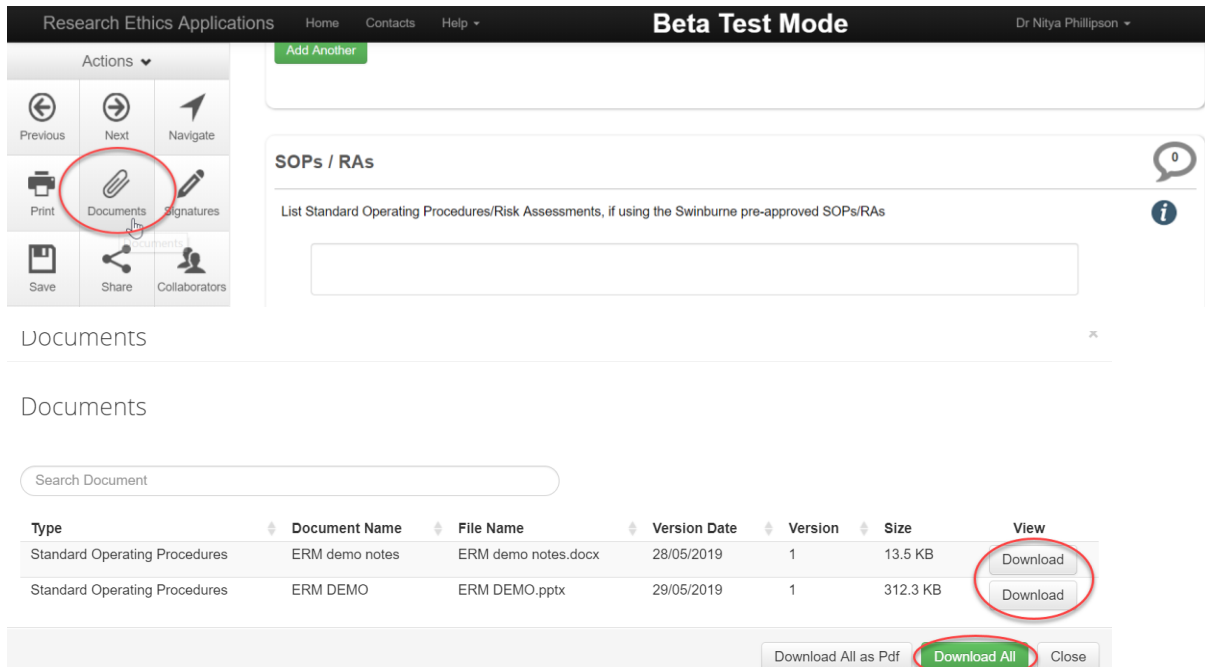
4 How to share and collaborate on a biosafety application

- To share your application with other collaborators, click on the Share icon on the LHS action tab
- A pop-up box will appear. Enter the email address of the collaborator.
- Select permission (you can select multiple options)

- o Read - person can read the application
- o Write - person can add content to the application
- o Submit- person can submit the application (see signature section for more information on submission)
- o Share - person can go on to share the application with others and assign these permissions forward
- o Create all sub forms - person can create sub forms like annual reports and adverse event
- o Receive notifications - person will receive notifications about the application.
- Do this for multiple collaborators by clicking on the addition button and repeat for additional collaborators.
- All persons with a @swin.edu.au or @swin.edu.my email address will immediately be set up with access to Swinburne ERM. If they do not have an @swin.edu.au an invite button will appear, the person will receive an email indicating how to obtain access to the system.
- To remove a collaborator, click on the minus button.
- Click share to finalise. This can be modified at any time. Please note you cannot click share if you have empty collaborator sections present.
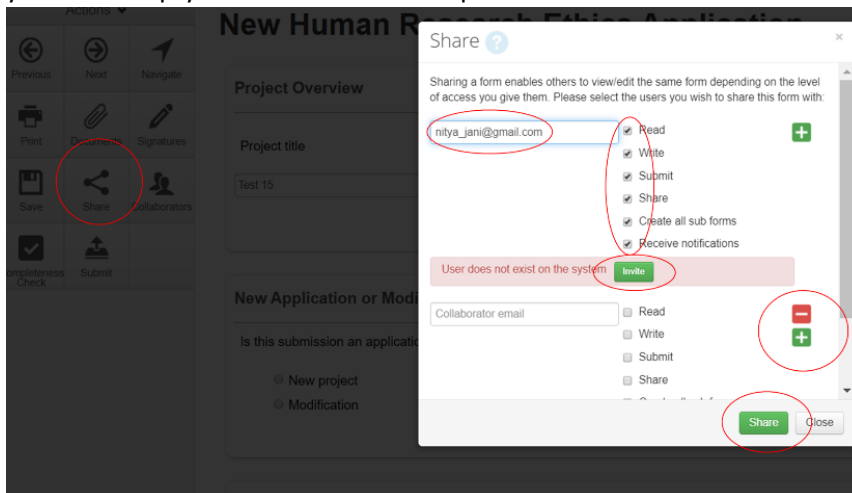

- To review your collaboration or edit permissions click on collaboration icon on LHS actions tab. You can edit permission by clicking on edit permission button
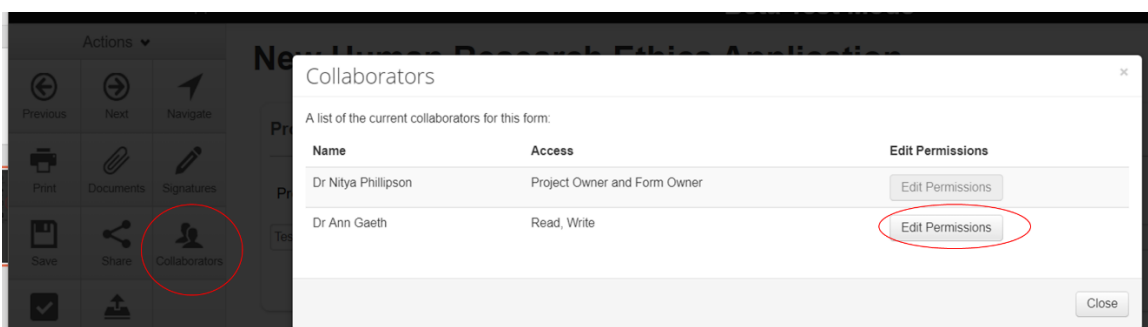

5 How to make comments on yours or a collaborator's biosafety application

- To make a comment for other researchers or collaborators to see click on the comment bubble on the top right-hand side of a question.

- Enter the comment you wish your collaborators to see. These will only be visible to your collaborators and not the committee reviewer
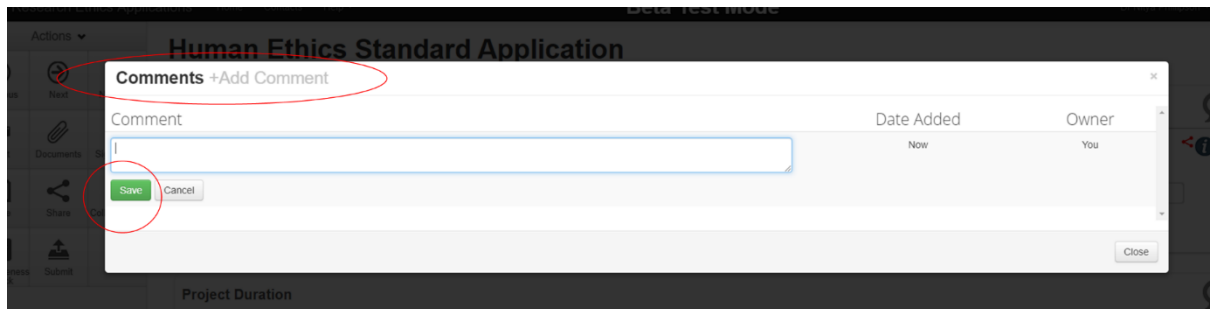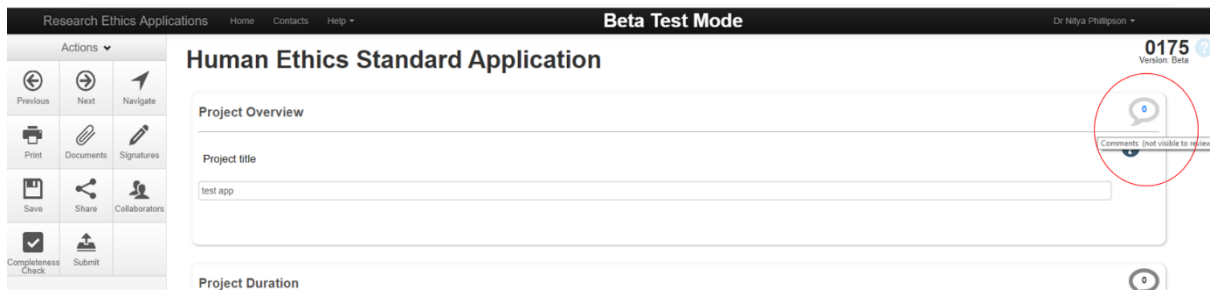
- To view a summary of comments, click on the Comments button on the LHS action tab
- A list of all comments will appear, you can click on these comments and it will take you directly to the question the comment refers to.
- You can edit or delete a comment by clicking on the comment and the delete button shows up or you can amend this comment.
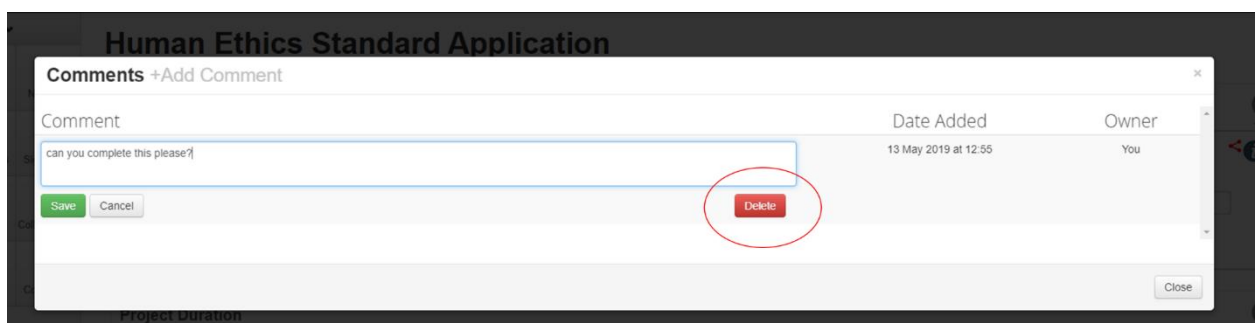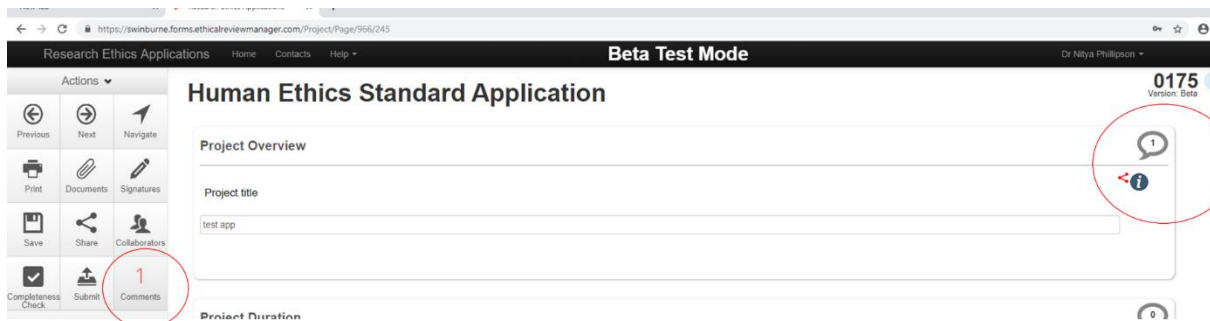
6   How to submit a Biosafety application

- Chief investigators (CIs) must sign off on SBC applications.
- Students or research assistants cannot act as CI, the student's primary supervisor should act as the CI

- To commence sign off, click on the navigate icon on the LHS actions tab to navigate to the Supervisor Declaration section of the application
- Once an application is submitted, an email will be sent to all ALL investigators and associate investigators listed as researchers on the application notifying that an application has been submitted with them listed as an investigator
- *The REO strongly recommends that the application be shared with all listed applicants with at least read permission.*

6.1 If the applicant is the CI

- Using the navigate icon on the LHS actions tab to navigate to the Supervisor Declaration section of the application
- The sign off question asks: Are you the chief investigator of this project
- If the applicant is the CI then then click yes.
- A completeness check will be undertaken. Sections that are incomplete will be highlighted. Click on the relevant section of the application which will indicate the incomplete section. The application cannot be submitted until all mandatory sections have been completed.
- A CI declaration will appear, this must be carefully read and if agreed to click on the submit button.
- Your application has now been submitted and will be locked. The REO will automatically receive this information and an automated email will be sent confirming submission.

6.2 If the applicant is NOT the CI

- Using the navigate icon on the LHS actions tab to navigate to the sign off section of the application
- The sign off question asks: Are you the chief investigator of this project
- If the applicant is NOT the CI then then click No. Please note students cannot act as CIs this should be the student's primary supervisor or project lead.
- You will be asked to request a signature of the CI, click on request signature
- Enter the CI's email address, a message for the CI and click on Request
- The CI must also be listed an applicant on the application otherwise an error message will appear.
- When you click on request, a completeness check will be undertaken. Sections that are incomplete will be highlighted. Click on the relevant section of the application which will indicate the incomplete section. The application cannot be submitted until all mandatory sections have been completed.
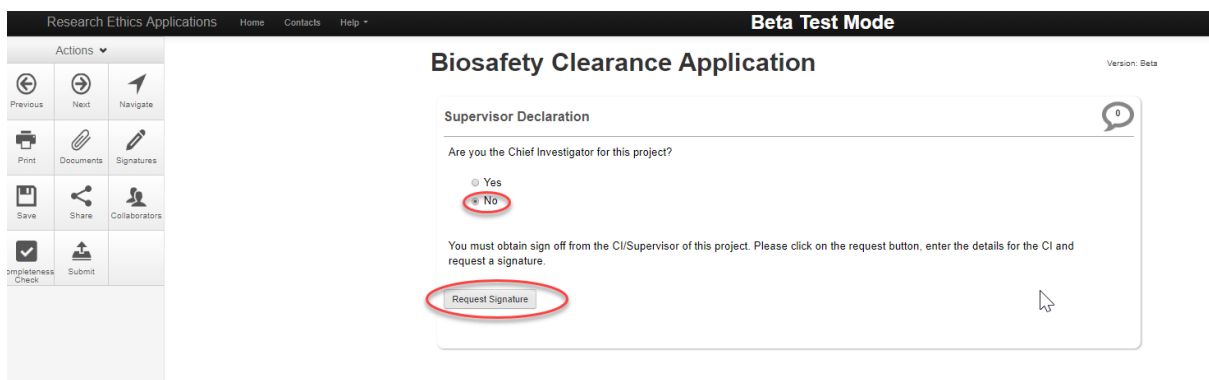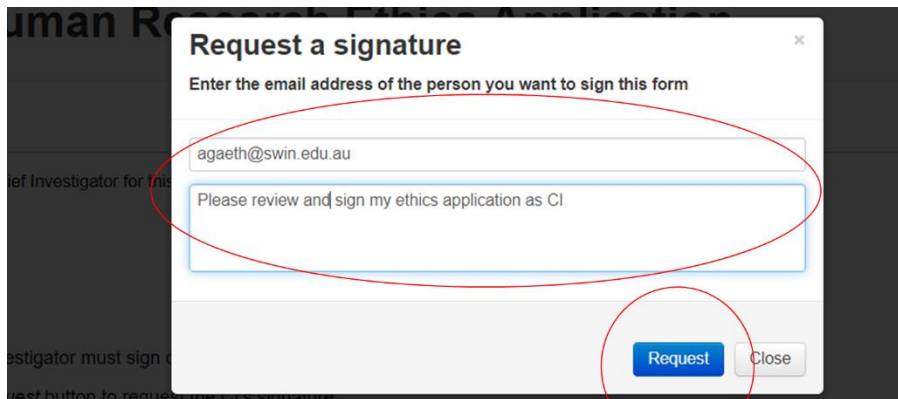
- The CI will receive an email requesting sign off. The link in the email will take the CI to the project (sign in required using Swinburne single sign on user ID (name@swin.edu.au) and password.
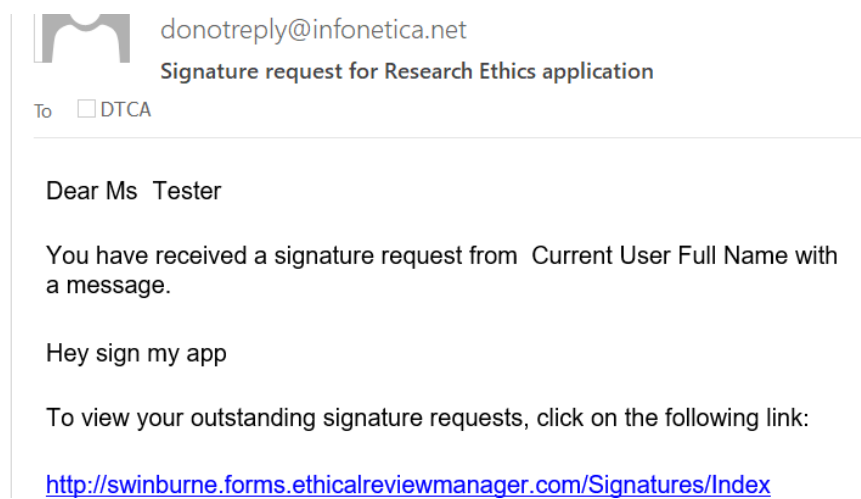

- **When the CI signs off on the application you will receive notification via email. You must then go back to the application and select submit in the LHS action tab.**
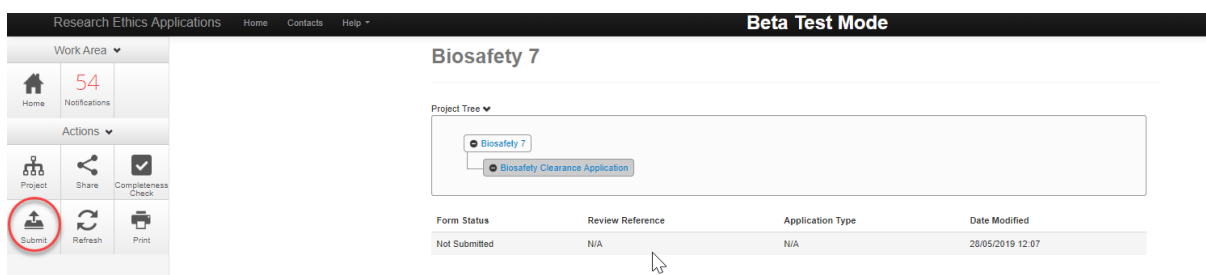

6.3   Signing an SBC application as CI

- You will receive an email asking you to sign in to ERM and sign off on an application
- Click on the signatures tile on the Work Area
- Here you can see all applications waiting on signatures and previously signed
- Click on view application- you will have read only access to the application.
- If you are happy with the application click on the sign icon on the LHS action tab
- You will be prompted to renter your email address and password.
- An email will now be sent to the applicant indicating sign off.
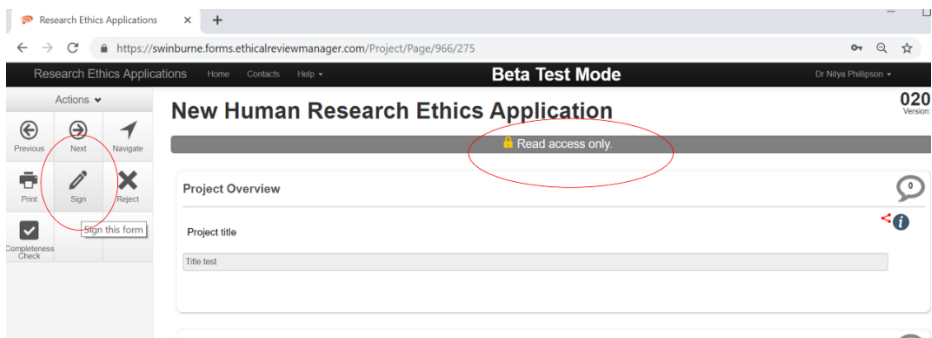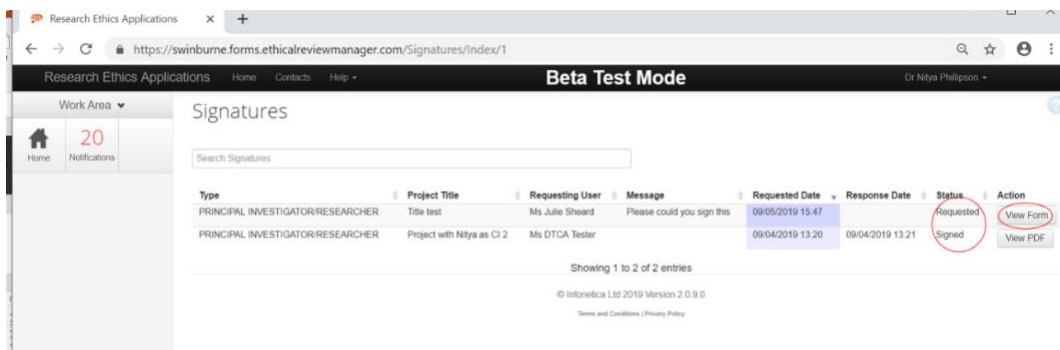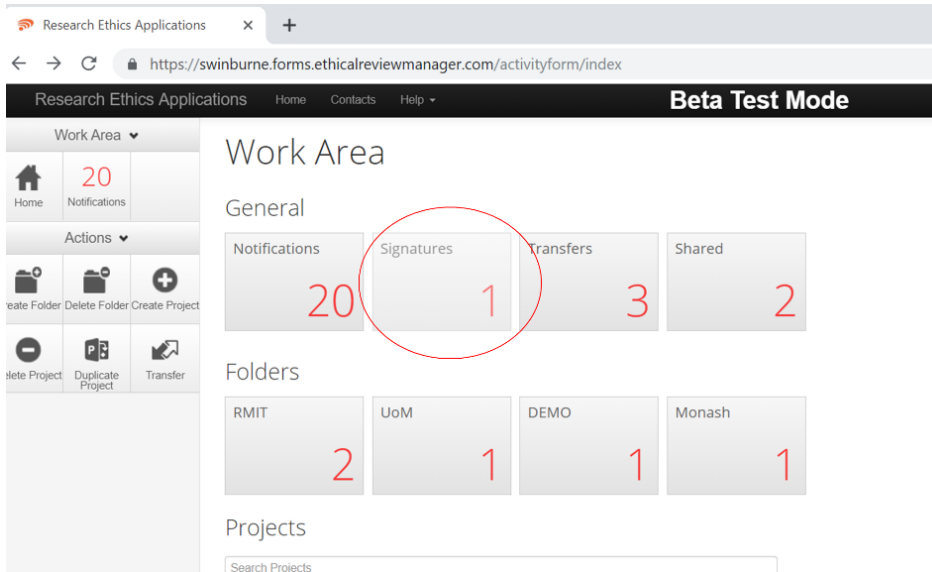
- If you do not wish to sign off on the SBC application. Click on the Reject icon on the LHS actions tab.
- You will be prompted to provide feedback to the applicant. This will be sent in an email to the applicant and the form unlocked for changes.
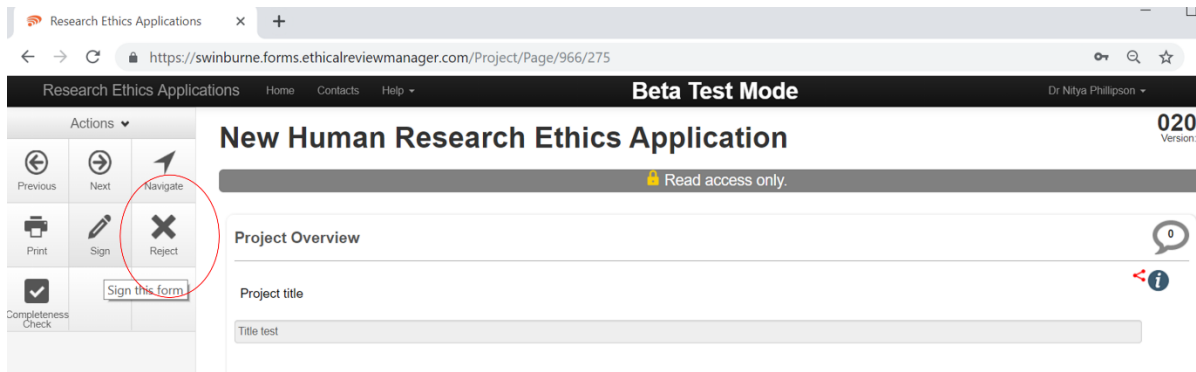
7 How to organise your projects

- You can create custom folders to store your SBC applications.
- In the work area click on create folder
- Name the folder as you wish
- You can then drag and drop applications out of the list of all applications into relevant folders, the folder will turn yellow when you are about to drop something into it
- Please note that when you search for projects in this list of all applications any projects placed in sub folders will not show up.
- To move a project, click into the folder and select move folder button on LHS action tab. This will then allow you to move the project into other existing folders or the work area.
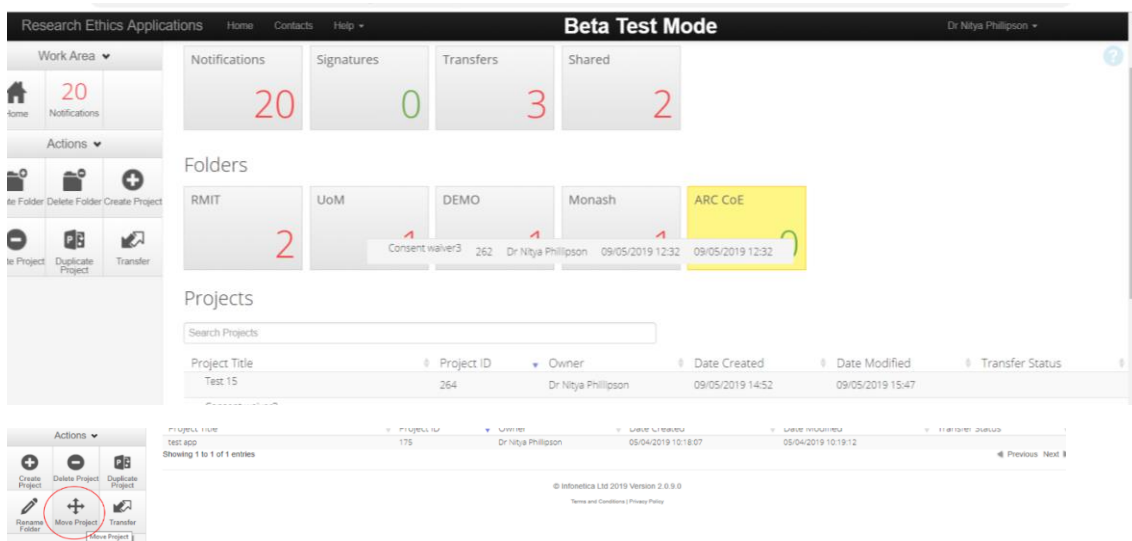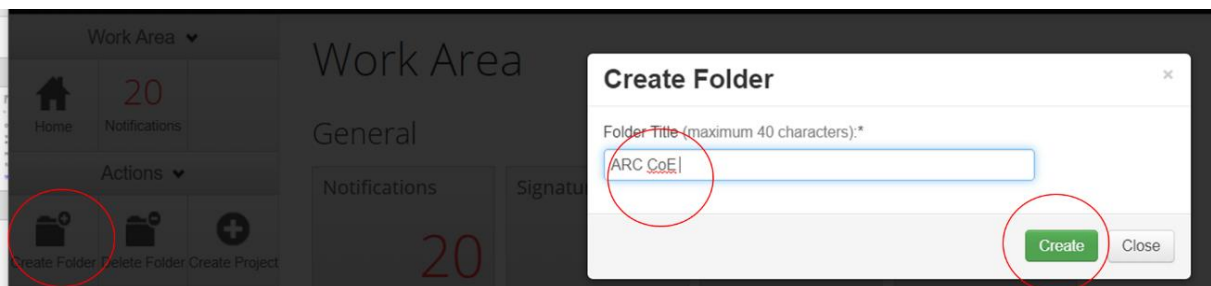
8 How to duplicate an existing application

- Click on Duplicate project in the LHS actions tab of the work area

- Select the application you wish to duplicate out of the drop-down list. All applications within the work area will be listed. If the application you wish to duplicate is in a folder, enter that folder and then select duplicate. The applications listed in the drop down available to be duplicated will now only be for those in the folder you are accessing this button from.
- Enter a new title for the duplicate application
- You can now amend the duplicated application as appropriate
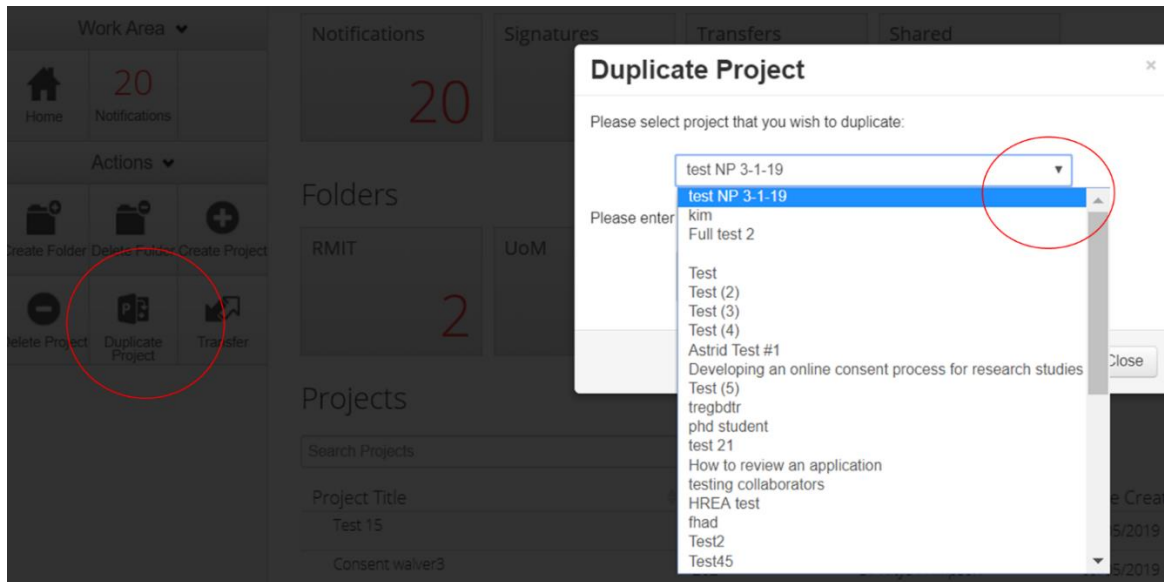
9 How to search for a project

- The work area has all your applications that are not in folders in a searchable list. To search for a particular application, type in the title or key word. The list of projects will start narrowing down as you type.
- Please note that projects in folders cannot be found using this search bar. For that you must enter the project folder and search within that folder.
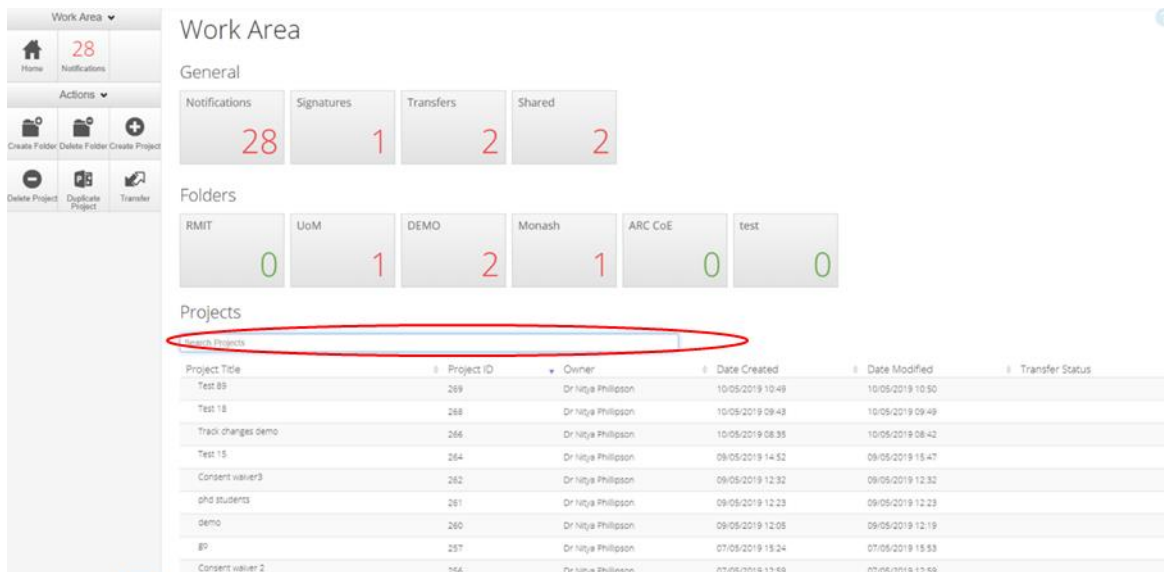
10 How to transfer an application

- If you are no longer CI on a project or you are leaving Swinburne, you will need to transfer you project to a new CI
- Click on the Transfer icon on the LHS of the actions tab in the work area
- Enter the email address of the new CI and a message regarding the transfer, then select the applications you wish to transfer.
- The new CI will receive an email indicating the transfer. The research ethics office will also be notified about the transfer so they can support the old and new CI in any changes to documentation required.
- You will no longer have access to a transferred application.
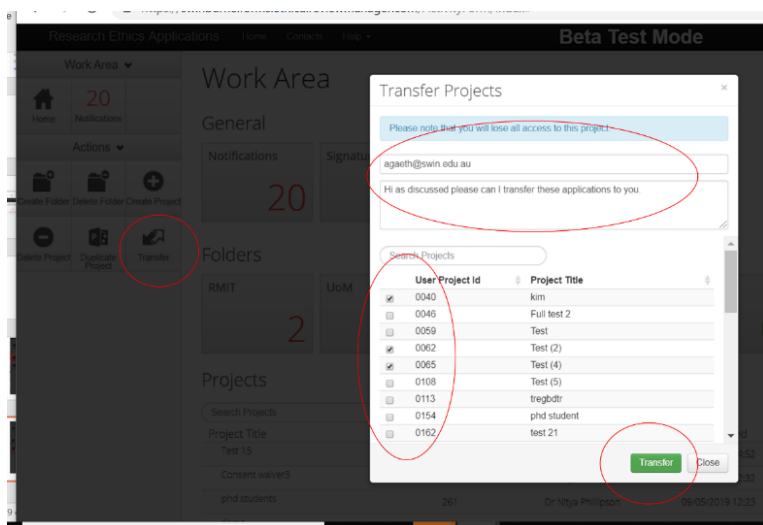
10.1 How to accept or reject a transferred application

- Go to the transfer icon on the work area
- This will show you all transfers, transfers requiring your action will be highlighted in yellow. To accept a transfer, click on view project
- You can accept or reject the transfer using accept transfer and reject transfer icon on the LHS actions tab.

11 How to receive and response to committee feedback

- You will be notified via email when you have received feedback from the SBC office or committee.
- This email will contain a link to the SBC application in ERM and attachment that includes a list of the comments made in the application
- Log into ERM and make any relevant changes to the sections required.
- To see all the comments made, click on the Reviewer comments button on the LHS actions tab
- A list of all the comments made about specific questions will pop up
- Clicking on the comment will take you to the page of the application form where the comment has been made. You may need to scroll down to find the question that the comment pertains to
- Click on the comment bubble on the top RHS of the question to view the question.
- Amend the response in the application accordingly.
- To see previous comments related to previous submission click on show previous comments.

11.1 Upload any changed documents

- If changes are required to Risk assessment or SOPS use track changes to make any relevant changes to these document
- Upload the response to queries document and any amended documents in the relevant section of the application.
- **Resubmit the application**. Note if you are not the CI you will be required to obtain sign off from the CI on this resubmission. To do this see section 6.

12 Modifications

- All modifications to approved SBC applications must be submitted and approved prior to implementation
- Go into the application you wish to modify and click on Create sub-form on LHS actions tab
- From the drop down list, select Biosafety Modification Request and click Create
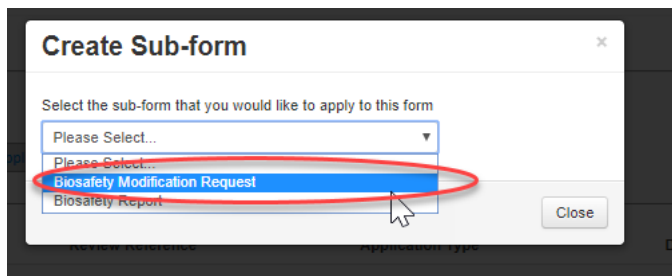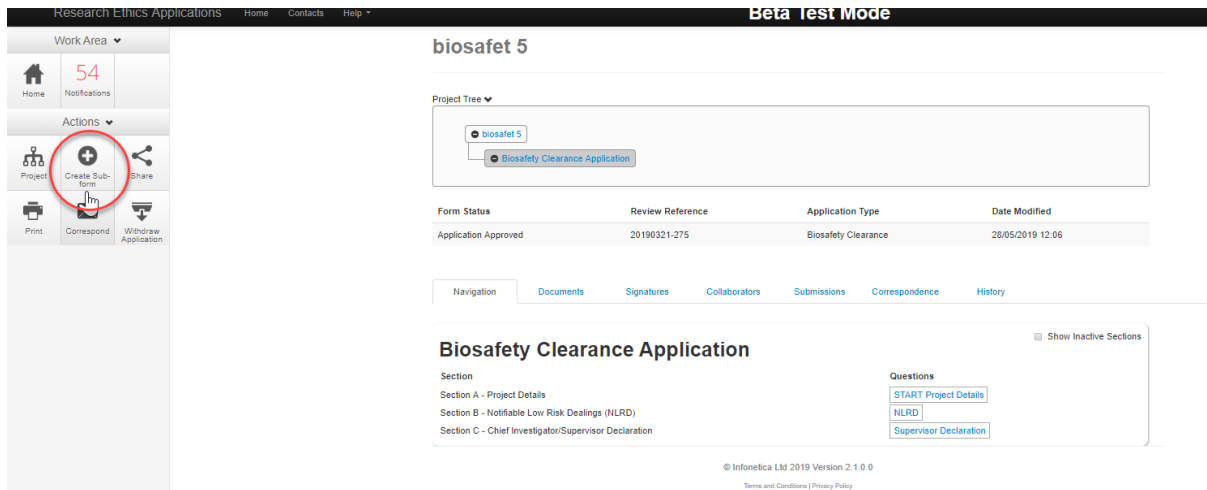
- Work through the modification form, use the navigate, next or previous button to navigate through the form.
- Submit the modification form by clicking on the Submit button.
- You will be notified via email if we have any queries about your modification or when you modification is approved.
- To see all modifications made to an existing application, go to the application in ERM and in the project tree you will see the modification made to date.

13 Annual/Final Reports

- You will receive an email from the system 30 days before a report is due and the day before a report is due. You will also receive reminder emails after the report is due if you fail to submit one.
- Sign in to ERM and go the project requiring a report (email will indicate project number and title)
- Click on the Create sub form button in the LHS action tab
- Select the Sub form: Biosafety Report

- Work through the report starting at Section A. Some of this data is auto-generated from the associated SBC application
- Navigate through the form by clicking the Next or Previous button or Navigate button on the LHS of the Action tab.
- To share the annual report form with investigators click on the Share button on the LHS Action tab. See section 4 on more information on using the Share functionality.
- To submit click on the submit button on the LHS action tab.
- If you have any questions please contact resethics@swin.edu.au