University of South Australia

User Guide

Human Research Ethics Applications
My Research Management (MyRM)

Applicant Guide

Version 6

UniSA Research Office

For further information or assistance please contact the UniSA Research Office Research Ethics and Compliance team: e-mail humanethics@unisa.edu.au, ph. 8302 6330

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University of South Australia

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OVERVIEW: HUMAN RESEARCH ETHICS APPLICATIONS

All staff and students at University of South Australia who wish to undertake a research project involving humans (including direct collection of data, accessing data from databases and/or collection of human tissues/samples etc.) must apply for ethics approval from the University of South Australia's Human Research Ethics Committee using the My Research Management (MyRM) system.

Researchers must be familiar with the following documents before commencing an application:

a. the *National Statement on Ethical Conduct in Human Research* (https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007- updated-2018)

b. the *Australian Code for the Responsible Conduct of Research* (https://nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018).

The University's Human Research Ethics webpage provides further information on the ethics application and review process: https://www.unisa.edu.au/research/integrity/research-ethics/human-ethics/

> ***Note****: The images displayed in this user guide were captured using fictitious examples of a human research ethics application and do not contain information or details of actual applications.*

1. GETTING STARTED

1.1 Logging in

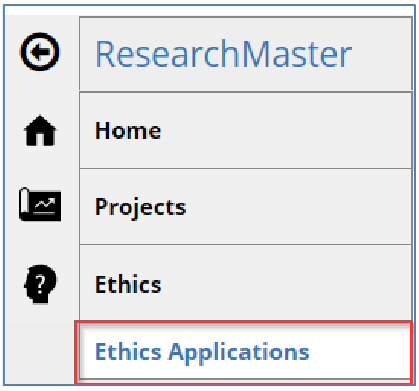
Navigation: https://rme.unisa.edu.au/rme

Action: Enter your UniSA network **Username** and **Password** and click the Login button.

Result: User is logged into the **MyRM** system and the Home page is displayed.

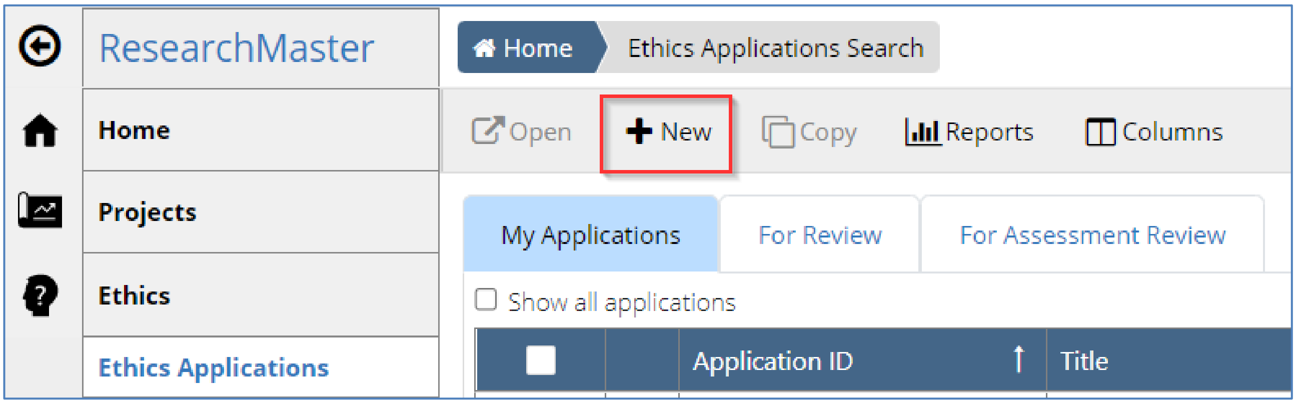
1.2 Creating a new application

Navigation: On the main ResearchMaster modules menu, select **'Ethics Applications'** under the **Ethics** section heading.

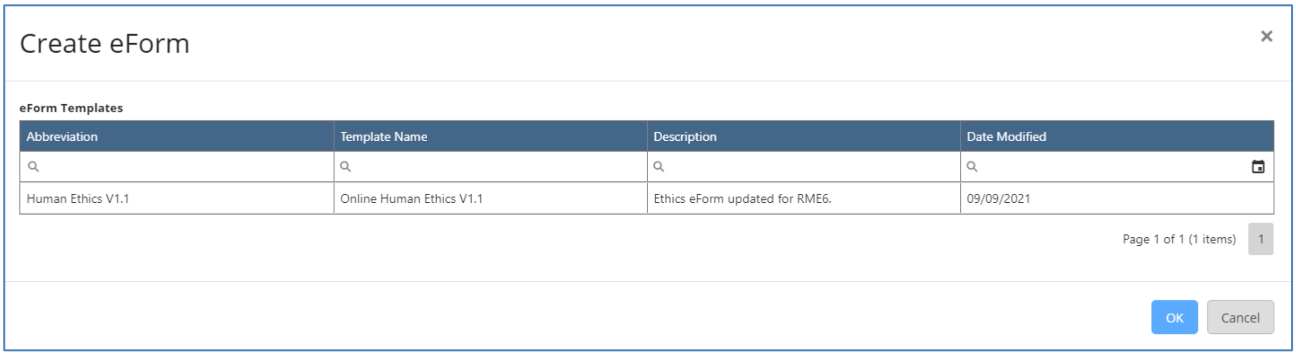


***Note**: Depending upon your user access permissions you may or may not see the Projects Section in the ResearchMaster modules menu*

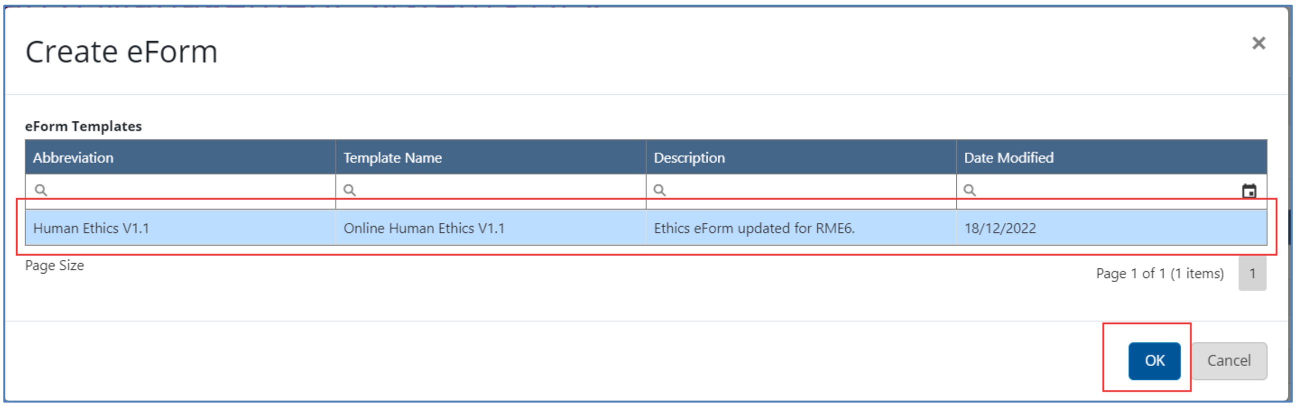
Action: On the top menu bar, click **+New**



Result: The Create eForm window appears.

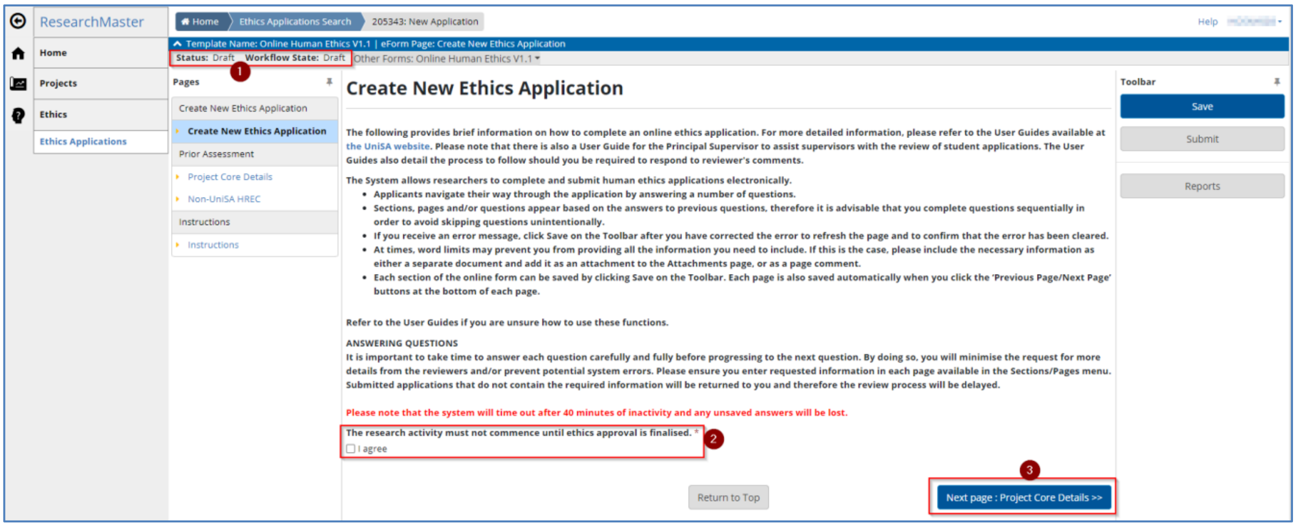


Action: Click the template name so that the row is highlighted. Click **OK**.



Result: A new application is created and opens with Application Status: Draft, Workflow State: Draft (❶ in image below)

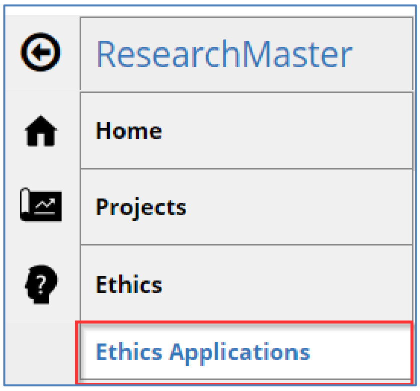
Action: On the Create New Ethics Application page, read the information and tick **'I agree'** (❷) in the consent form and then click the **Next page** button (❸)



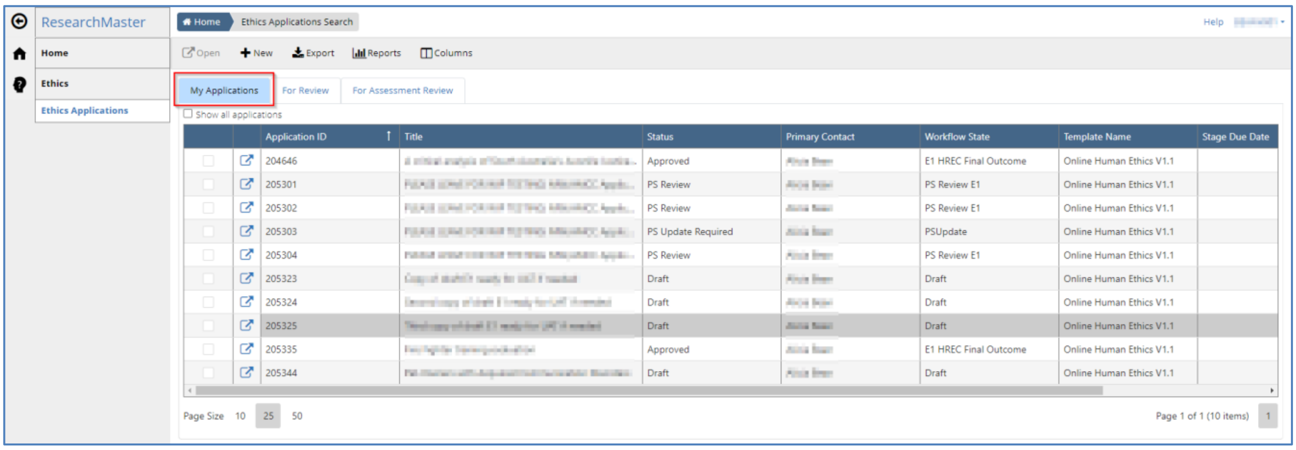
Result: The Application is ready to fill out.

1.3 Accessing existing application(s)

Navigation: On the main ResearchMaster modules menu, select 'Ethics Applications' under the Ethics section heading.



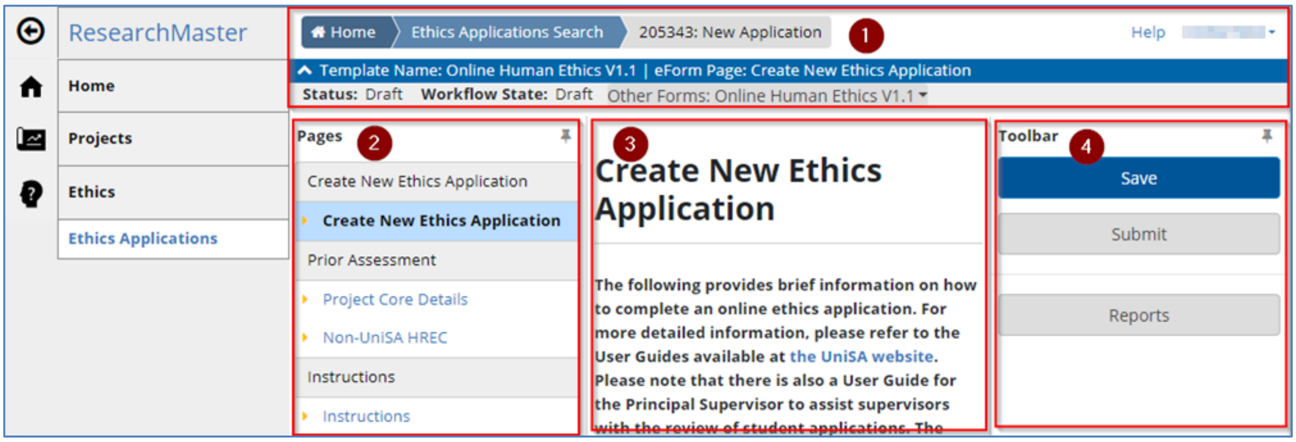
Result: The Ethics Applications page opens and the 'My Applications' tab is activated. Applications available to the user are displayed.



2. COMPLETING AND SUBMITTING AN ETHICS APPLICATION

2.1 Navigating the application

There are **four components** to the application.

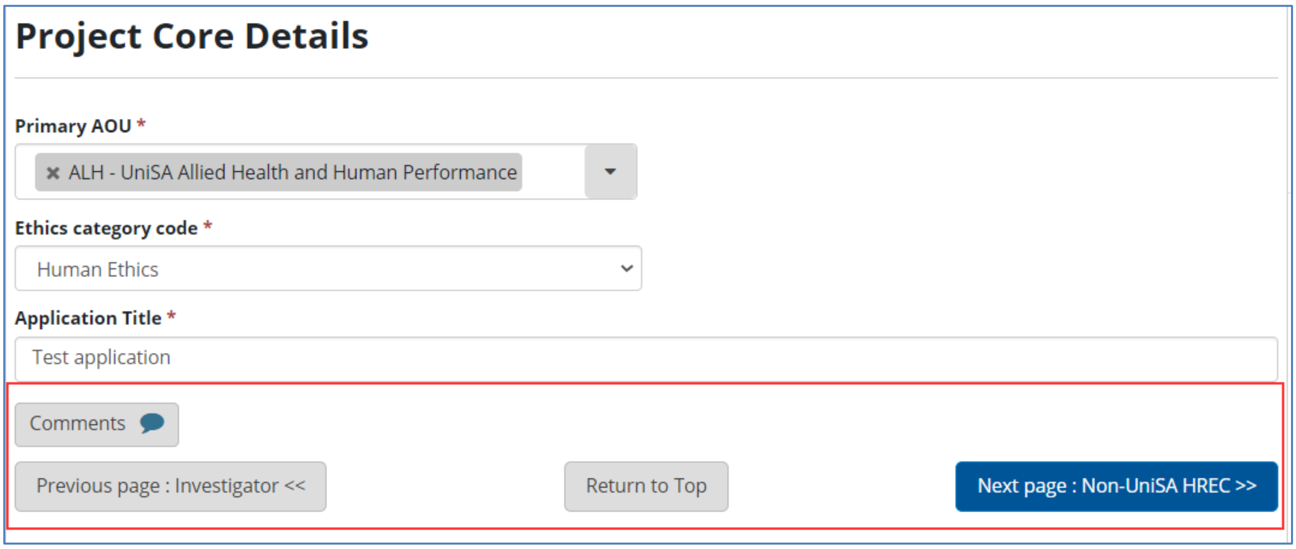


❶ **eForm Header:** Located at the top of the screen, the eForm Header displays:

a) the breadcrumbs (Home > Ethics Application Search> Ethics Application ID: Ethics Application Title);
b) Help menu;
c) User Session (note, user name is blurred in this image). Click your user name to find the Log Off;
d) Application Status and Current Workflow State;
e) Template Form name.

❷ **Navigation Panel:** Located on the left-hand side of the application, the Pages section provides access to sections within the application, displaying both the Section Headings and Pages. The pin can be used to expand/collapse the Pages menu allowing a wider space to view the form page content.

❸ **Application Content:** The main section of the screen, displays the Page name bolded at the top of the page, the application questions and responses. The Comments button at the bottom of each page (see image below) displays the number of comments included that require response. There are also previous page/ next page buttons at the bottom of each page content for ease of navigation.



❹ **Toolbar:** Located to the right-hand side of the screen, the Toolbar provides actions (e.g. Save, Submit, Withdraw, etc) available at each workflow stage. A Reports button is also located under the Toolbar for generating a printable copy of the application form or comments.

2.2 Answering questions in the application

Questions within the application require answers in different formats – Yes/No, date, tick box options, numerical fields and text responses. The applicant can answer questions in any order. However, some questions are dependent on the answer provided to an earlier question. As such, it is advisable that you complete questions sequentially in order to avoid skipping sections unintentionally.

> ***Note**: Applications can be completed progressively and are not required to be completed in one sitting.*

Advice and assistance:

- If an applicant requires ethics advice when completing the application form, they can contact the Research Ethics Advisor (REA) for their Academic Unit. A list of REAs and their contact details is available at: https://mymailunisaedu.sharepoint.com/teams/rch/ris/risethics/Pages/rea.aspx (login required).
- The Human Research Ethics Officers in the Research Ethics and Compliance team can assist with System troubleshooting and general ethics enquiries: email humanethics@unisa.edu.au, ph. 8302 6330.
- Please note that students should consult with their Supervisor in the first instance.

Saving the application:

- The answers entered on each page are saved automatically when you click on previous/next page arrows to navigate through the form.
- The application can also be saved at any time by clicking Save on the Toolbar.
- It is also recommended that if you receive an error message, click Save on the Toolbar after you have corrected the error to refresh the page and to confirm that the error has been cleared.

Other matters to note when completing the application:

- Mandatory fields are marked with an Asterisk (*) at the end of the question. Note that there are two mandatory attachments: 1. Reference List and 2. Research Tools (or reasons as to why there aren't any).
- Some questions will also have Help relevant to the question as indicated by a (?) at the end of the question.
- At times, word limits may prevent you from providing all the information you need to include. If this is the case, please include the necessary information as either a separate document and add it as an attachment to the Attachments page, or as a page comment.
- It is important to take time to answer each question carefully and fully before progressing to the next question. By doing so, you will minimise the request for more details from the reviewers and/or prevent potential system errors. Please ensure you enter requested information in each page available in the Sections/Pages menu. Submitted applications that do not contain the required information will be returned to you and therefore the review process will be delayed.

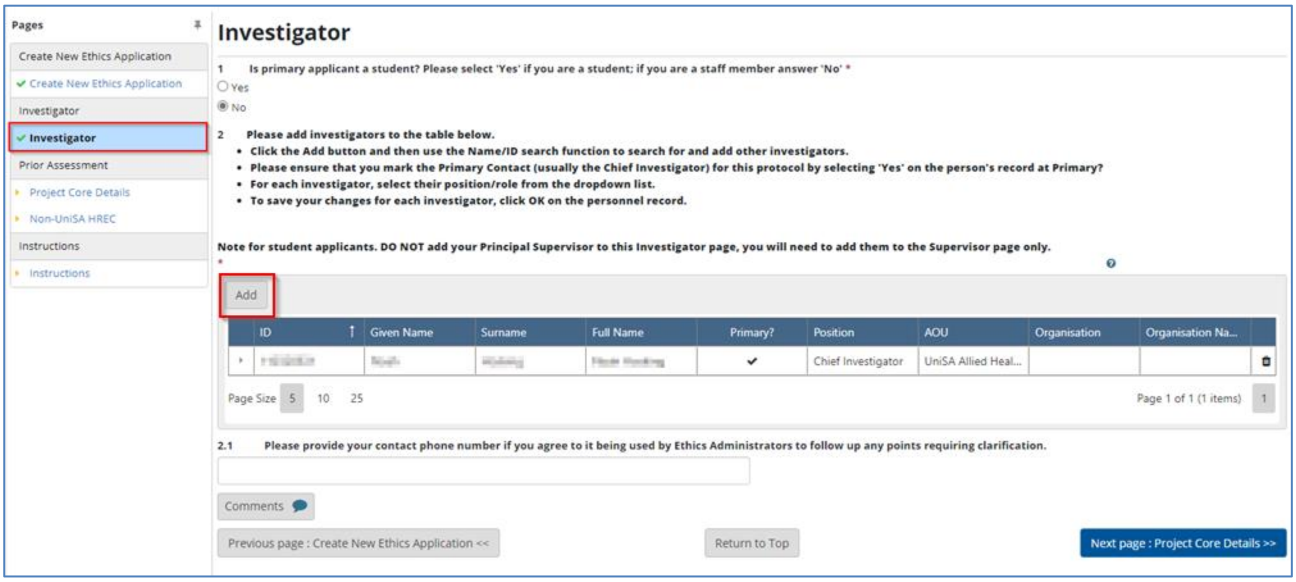
2.3 Adding investigators

Navigation: Open the **Investigator** page.

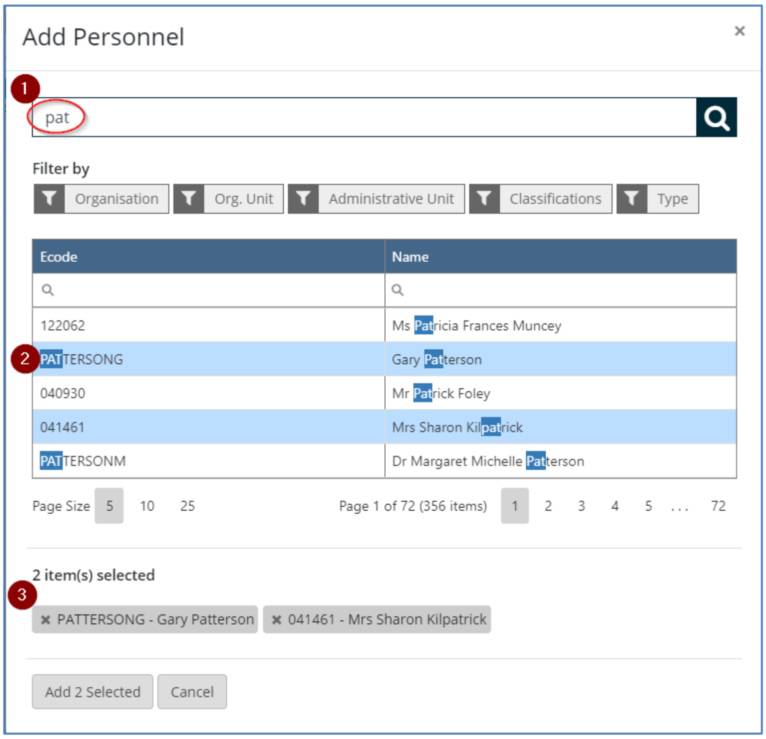
Result: The person who created the application will automatically be listed as an Investigator, but other members of the research team must be added manually.

2.3.1 To add an additional investigator

Action: Click the **Add** button above the Investigator table.



Result: A pop up **Add Personnel** panel appears.



2.3.2 To search for an investigator

Action: In the Search bar (❶) on the Add Personnel pop up panel, you can type any part of a person's name or ID number as a quick search.

Result: All records that include the text string (letters or numbers) entered will appear in the list of resulting records.

> ***Note:*** *You can also use the specific search parameter options, to search by ID (ECode), Name, Academic Unit (Org. Unit), etc*

2.3.3 To select a person

Action: To select a person click on their name or ID in the list of results (❷).

Result: The selected person's row will highlight and their record will display beneath the table under 'N' item(s) selected. (❸)

2.3.4 To add the person to the list of personnel in your application

Action: Click on the button (❹) 'Add 'N' Selected

Result: The people are added to the record.

2.3.5 Selecting the Primary Investigator and completing investigator details

Only one person can be the **Primary Investigator**. As a default, the applicant (person that created the form) is assigned the role of Chief Investigator and Primary Investigator upon creation of the application form.

There may be more than one **Chief Investigator**. Any person assigned the role of Chief Investigator can view and edit the application in the system. Any person assigned as Other Investigator can view the application but cannot edit it.

> ***Note****: If the applicant is a student refer also to Section 2.3.9 Student applications and adding the Principal Supervisor.*

2.3.6 If the applicant is not the Primary Investigator

> ***Note:*** *This step is only required if the applicant is not the Chief Investigator.*

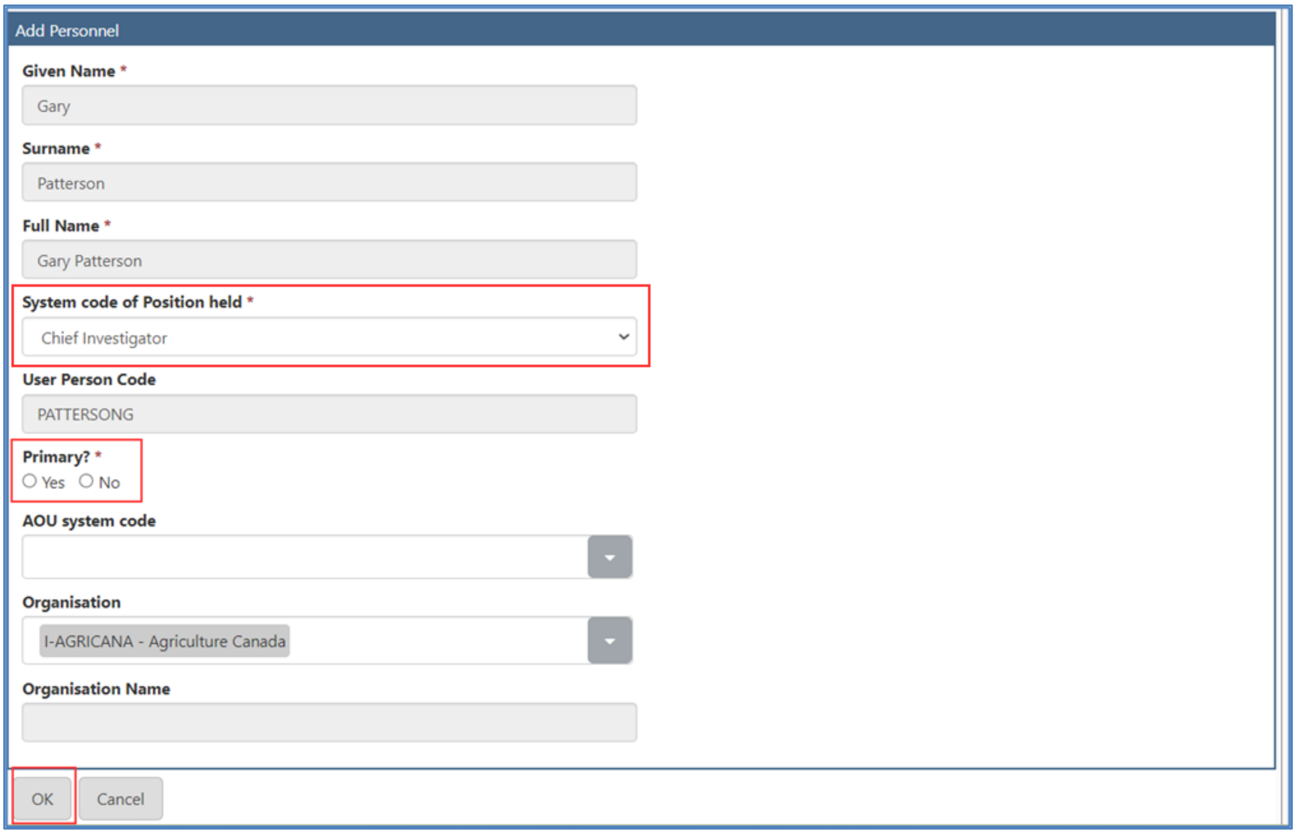
Action: Open the applicant's record, select No at **Primary?**, click **OK** to save. Find the correct person to set as Primary Investigator. Open their record, select **Yes** at **Primary?,** click **OK** to save.

Result: The correct person is now assigned as the Primary Investigator. The Primary Investigator is indicated in the grid of investigators with a tick under the column Primary?.

2.3.7 Completing investigator details

Action: Click the investigator record.

Result: Additional information about the investigator is displayed in the **Edit Personnel** panel.



> ***Note:*** *Each investigator added will have the default Position of Chief Investigator and Primary? will be unanswered. The fields Given Name, Surname, Full Name, User Person Code, AOU System Code, Organisation and Organisation Name are not editable and will display information held in the system's records where available.*

Action: For each investigator added to the record:

- select their Position (Chief Investigator / Other investigator / Supervisor)
- select Yes or No at the Primary? question (only one investigator can be the Primary Investigator)
- click OK to save the person and their details to the record.

Result*:* Investigator is added.

2.3.8 Removing an Investigator

Navigation: Open the **Investigator** page.

Action: Click the icon against the name of the Investigator to be deleted

	ID	Given Name	Surname	Full Name	Primary?	Position	AOU	Organisati...	Organisati...	
▸	[illegible]	[illegible]	[illegible]	[illegible]	✔	Chief Inves...	UniSA Clini...			🗑
▸	[illegible]	[illegible]	[illegible]	[illegible]		Chief Inves...	Research a...			🗑
▸	[illegible]	[illegible]	[illegible]	[illegible]		Other Inve...	Research a...			🗑
▸	[illegible]	[illegible]	[illegible]	[illegible]		Supervisor	Research a...			🗑
▸	[illegible]	[illegible]	[illegible]	[illegible]		Chief Inves...	Research a...			🗑
▸	[illegible]	[illegible]	[illegible]	[illegible]		Other Inve...	Research a...			🗑
▸	[illegible]	[illegible]	[illegible]	[illegible]		Supervisor	Research a...			🗑

Result*:* Investigator is deleted.

> ***Note:*** *Prior to the upgrade a warning message displayed "Are you sure you want to delete this record?". This warning message does not currently display and will be reinstated by the vendor in a future update.*

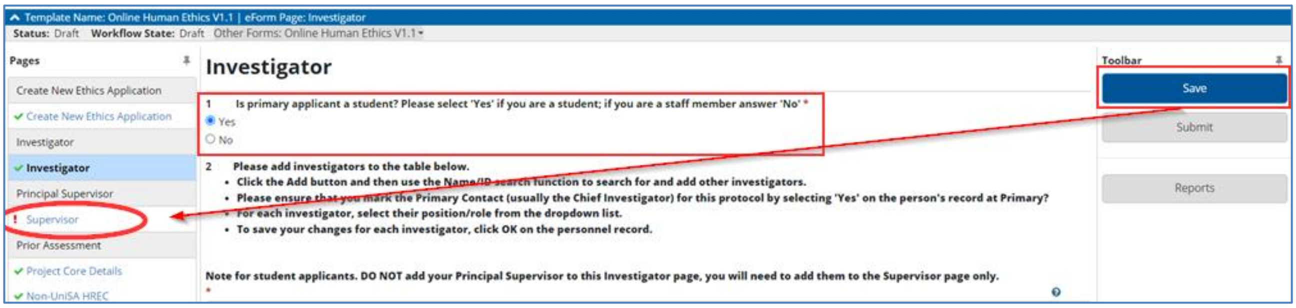
2.3.9 Student applications and adding the Principal Supervisor

If the applicant is a **student** they will also be required to identify their **Principal Supervisor** (i.e. the person responsible for reviewing the application) on the separate Supervisor page. This enables the application to be reviewed by the Principal Supervisor (and any concerns addressed by the student) prior to submission to the Human Research Ethics Officers.

Students should list any other supervisors on the Investigator page with Position set to Supervisor, noting that each person can only be included in the application once. A Supervisor is not required for staff applications.

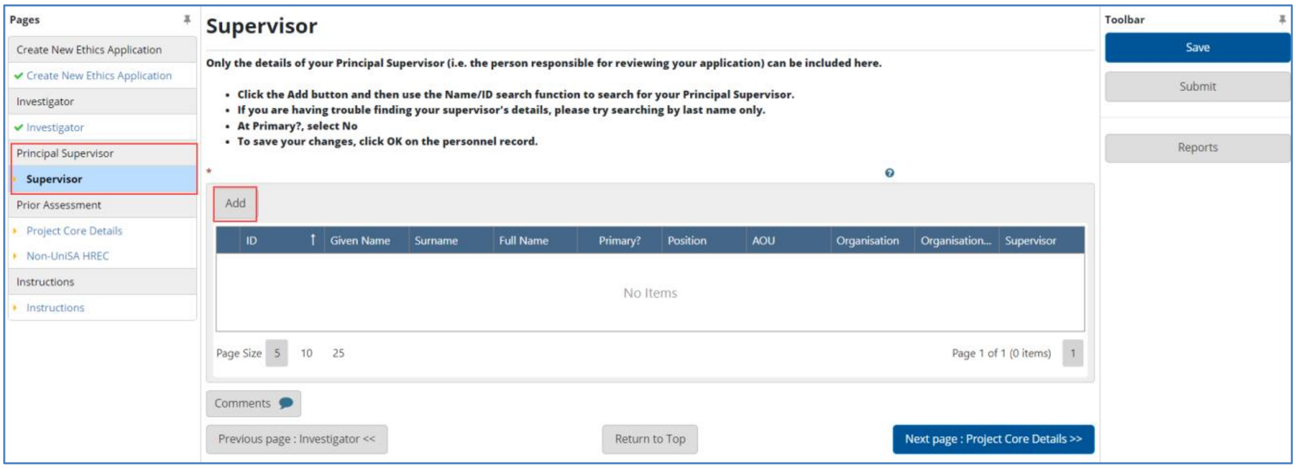
Navigation: Open the **Investigator** page.

Action: Select **Yes to Q1.** Is the primary applicant a student?. Click **Save** on the Toolbar.



Result: Principal Supervisor section and Supervisor page will be accessible.

Navigation: Open the Supervisor page.



Action: Search for and add the Principal Supervisor as per the steps at Section 2.3 Adding investigators. At Primary? select **No**. Check the details. Click **OK** to save the person and their details to the record.

> ***Note:*** *The Position defaults to Supervisor on the Supervisor page; Primary? must be set to No.*

Result: The Principal Investigator is added.

> ***Note:*** *Supervisors may also have a student ID (nine digits, e.g. 123456789) or an external ID (letters e.g. SMITHK). Ensure you select the Staff record of the Principal Supervisor (six digits). If the incorrect type of ID is entered then your Supervisor will not be able to review your application.*

2.3.10 Removing the Supervisor

Navigation: Open the **Supervisor** page.

Action: Click the icon against the name of the Principal Supervisor to be deleted.

Result*:* Principal Supervisor is deleted.

> ***Note:*** *If the applicant is a student a Principal Supervisor must be identified on the Supervisor page.*

2.4 Attachments

The Attachments section allows you to upload documents to support your application. This includes, but is not limited to:

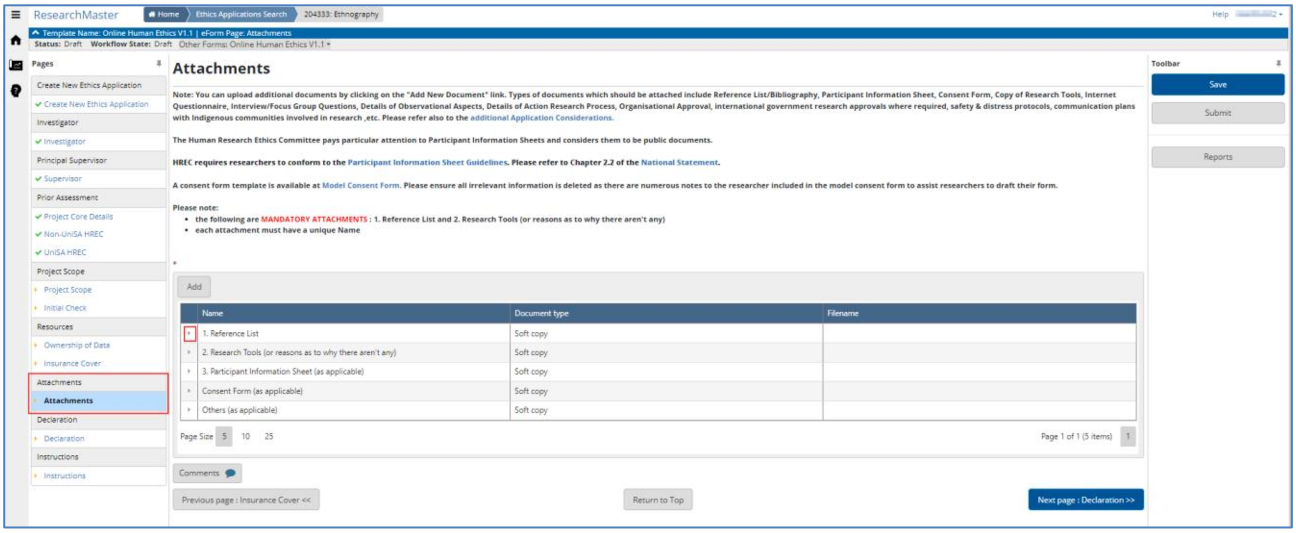
- A list of key references
- The research tools:
  - Questionnaire(s)
  - Interview/focus group questions or topics
- The recruitment material:
  - Participant Information sheet(s)
  - Participant Consent form(s)

  - Recruitment flyer(s) / letter(s)
  - Scripts for recruitment telephone calls
- Copies of the approval letters received from organisations involved in the research
- A copy of the confirmation of insurance cover from UniSA's Insurance Officer (if required).
- If the application has already been approved by another institution's HREC: a copy of the full application and approval letter from the other HREC.

> ***Note:*** *The Attachments table includes a list of pre-labelled document Names (Reference List, Participant Information Sheet, Consent Form, etc) for the most common attachments. You can add your attachment to the relevant record and for any other attachments create a new attachment record (row). The Reference List and Research Tools (or reasons as to why there aren't any) are mandatory attachments.*

> ***Note:*** *Only the following filetypes can be uploaded: .pdf, .doc, .docx, .xls, .xlsx, .txt*

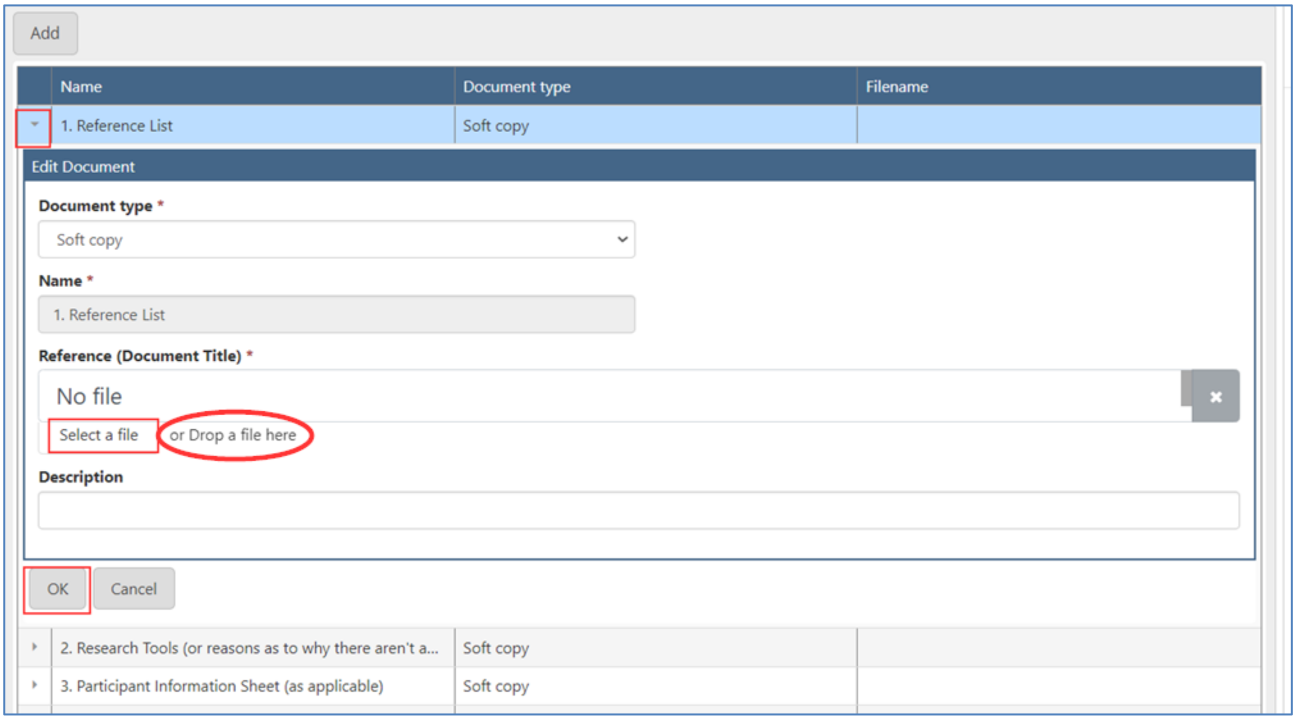
Navigation: Select the **Attachments** page under the Attachments section.



2.4.1 To add a document to a pre-labelled record in the Attachments table

Action: Click the arrow icon (▸) next to the Document Name for the document that you would like to upload.

Result*:* The **Edit Document** panel will appear.



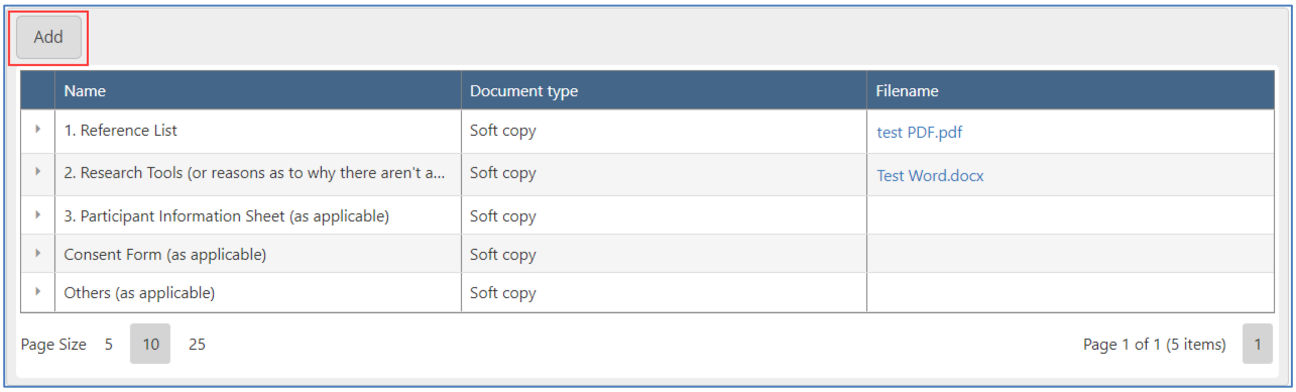
Action: Click the **Select a file** button to search and add the file, provide a Description (optional), and click the **OK** button to upload the file. Alternatively, you can drag and drop the file to 'Drop a file here'.

Result: The filename of the uploaded document will appear under the Reference (Document Title) field in the attachment panel and in the Filename column of the Attachments table.

2.4.2 To add other documents

To add further documents when all existing pre-labelled records (rows) are full or if the Name does not relate to the document you need to attach, you can create a new record.

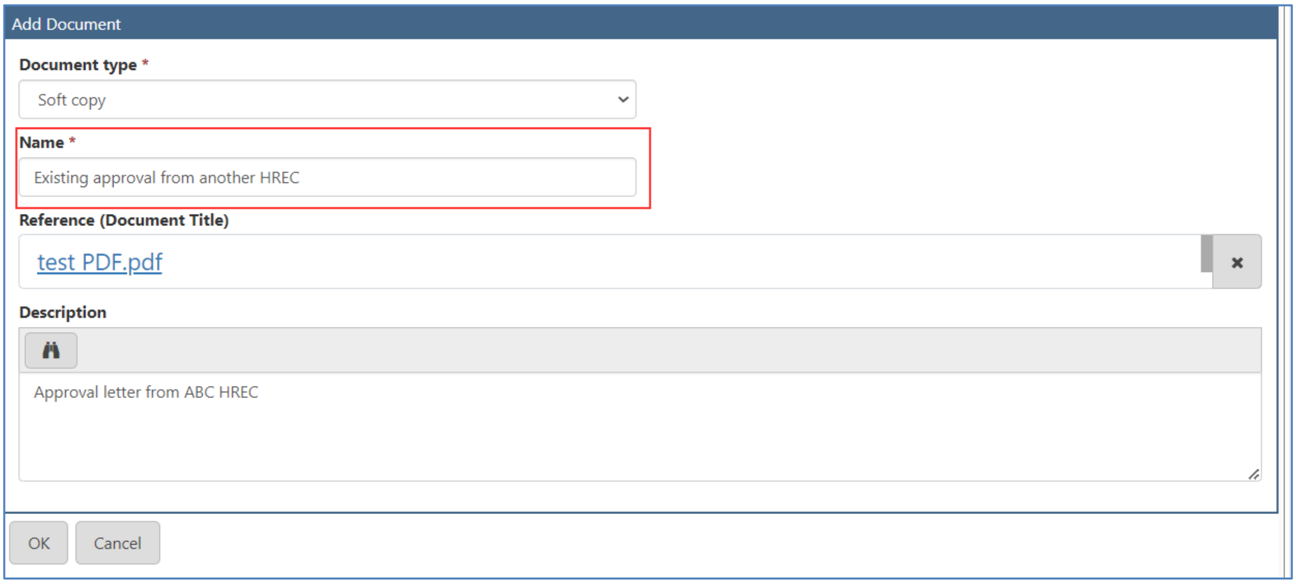
Action: Click the **Add** button at the top of the Attachments table.



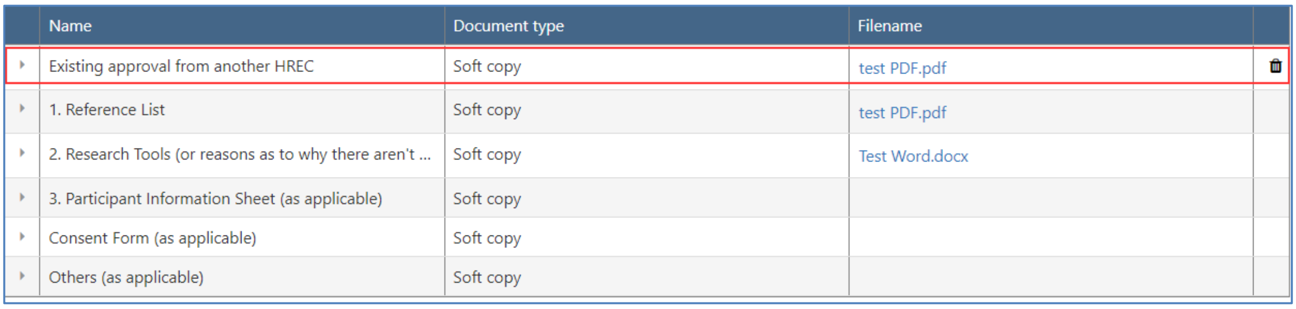
Action: Enter a document Name (for example, *Recruitment Flyer*) in the text box displayed. Upload the document. Add a description (optional). Click **OK** to save the new document type.

> ***Note:*** *Each attachment must have a unique Name. If you have, for example, several consent forms to attach you will need to either attach them as one multi page file or name each*

attachment differently (e.g Consent – Participant, Consent – Guardian, Consent – Nurse, Letter 1, Letter 2, Letter 3, etc)



Result: The new document is added.



	Name	Document type	Filename	
	Existing approval from another HREC	Soft copy	test PDF.pdf	
	1. Reference List	Soft copy	test PDF.pdf	
	2. Research Tools (or reasons as to why there aren't ...	Soft copy	Test Word.docx	
	3. Participant Information Sheet (as applicable)	Soft copy		
	Consent Form (as applicable)	Soft copy		
	Others (as applicable)	Soft copy		

Note: *In the previous system, some users encountered problems in the past with attachments not uploading correctly. The problem has not been identified in the new system, however, if you would like to ensure each attachment saves correctly it is recommended that you click Save on the Toolbar after each file is uploaded.*

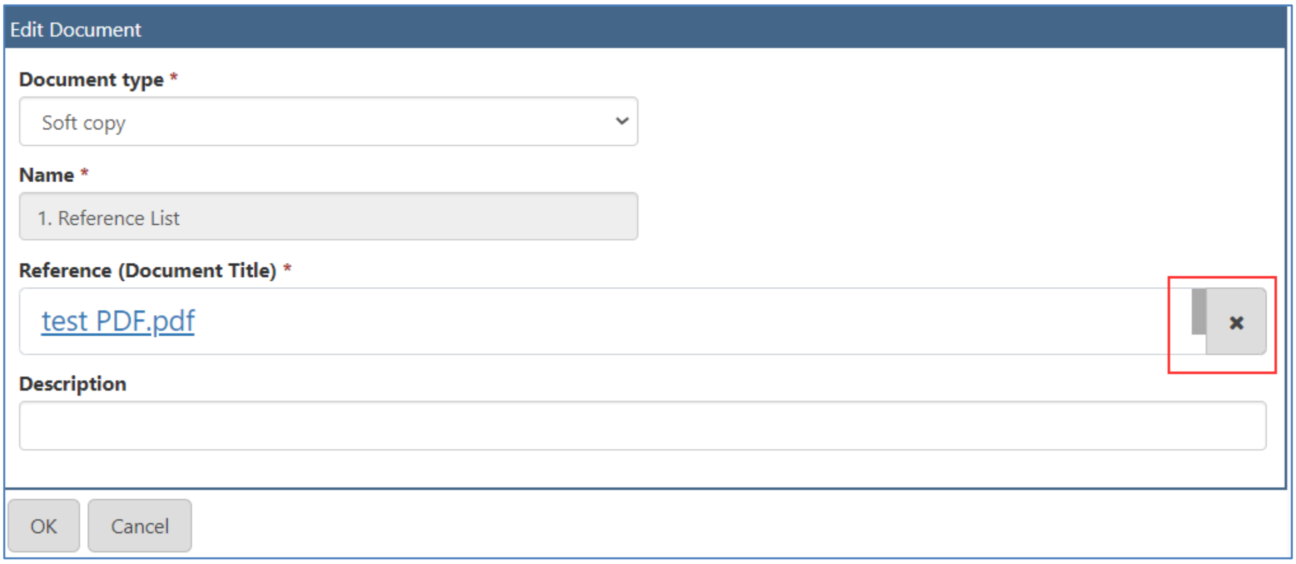
2.4.3 Replacing an Attachment

If you have uploaded the incorrect file onto one of the pre-labelled records (rows) you cannot delete the record (there is no icon for the pre-labelled records), you will need to replace the uploaded file with the correct one.

If you have uploaded the incorrect file to a record that you have created, you will see the icon for the record. You can follow the same steps as per below to replace the file (and save re-typing the Name and Description) or you can use the icon to delete the record completely from the table.

Action: Open the attachment record.

Result: The **Edit Document** panel appears.



Action: Click the button on the right-hand side of the Reference (Document Title) field where the file was uploaded.

Result: The filename is removed and the *Select file* or *Drop a file here* buttons are visible.

Action: Upload the correct document. Click **OK**.

Result: The new Filename is now visible in the Attachments Table.

2.4.4 Deleting Attachments

If you have added an attachment record you will see the icon for the record. The pre-labelled records cannot be deleted.

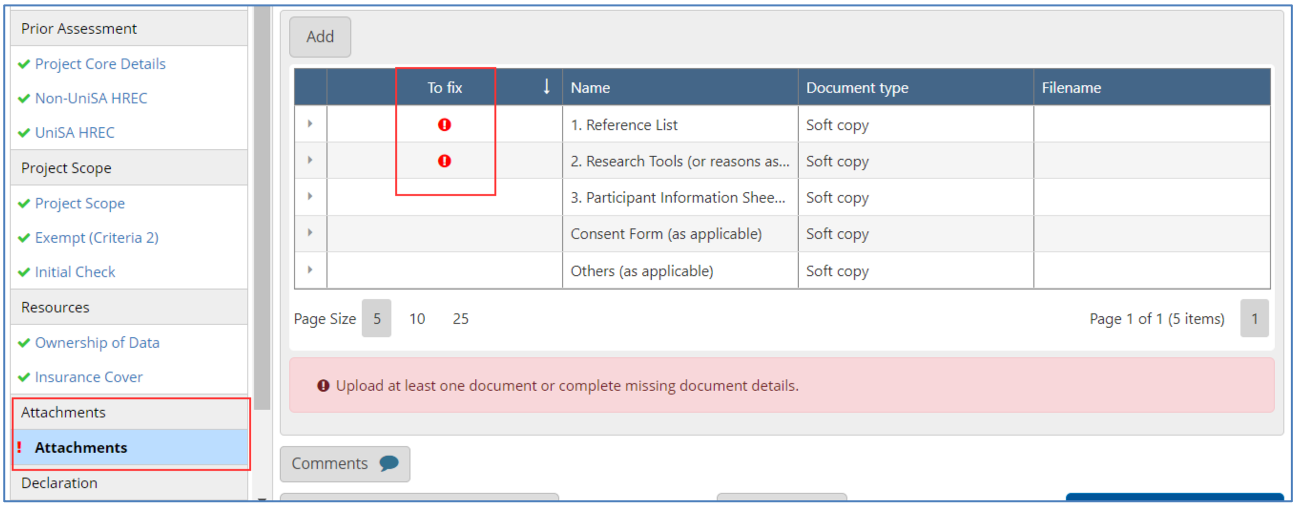
Action: Click the icon.

Result: The record (and attachment) is deleted from the Attachments table.

2.4.5 Error messages on Attachments page

Missing mandatory attachments

You will receive an error message if one of the two mandatory attachments have not been uploaded. A new column ‘To Fix’ will be visible and the records that require attention will be identified by an error icon ( ) and error messaging.

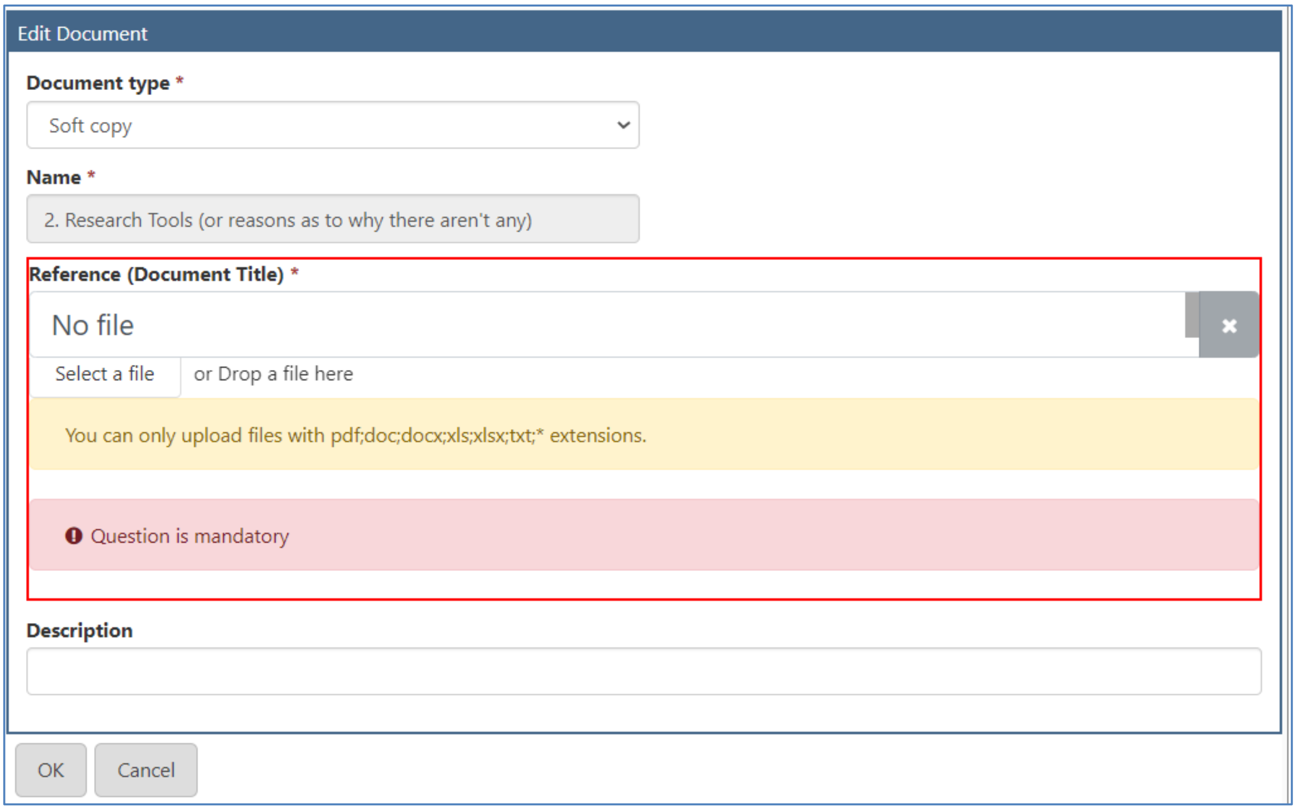


Action: Open the record that needs to be fixed and add the relevant attachment as per the steps at *Section 2.8.1 To add a document to a pre-labelled record in the attachments table*. Click **Save** on the Toolbar.

Result: If only one record required fixing, the *To Fix* column and error icon and messaging will disappear. If multiple records required fixing, repeat the steps to upload an attachment to each record and click **Save** on the Toolbar between each upload. Once all attachments have been uploaded the *To Fix* column and error messaging will disappear.

File type extension not permitted

Only the following filetypes can be uploaded to the system: .pdf, .doc, .docx, .xls, .xlsx, .txt. If you try to upload a file with another extension type you will receive an error message.



Action: Upload a filetype with one of the accepted extension types.

Result: The document uploads and the error message disappears.

2.4.6 Viewing Attachments

Navigation: Open the **Attachments** page.

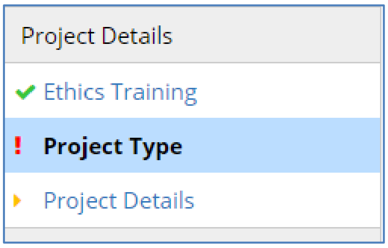
Action: Click on the **Filename**.

Result: The attachment will download to your computer. Open as per usual practice.

> ***Note:*** *The default Attachments table displays 5 rows/items. There may be more than one page for the uploaded attachments; this is indicated by the page and item counter at the bottom of the Attachments table.*

2.5 Submitting a completed application

The Human Research Ethics application can only be submitted when all mandatory questions in the form have been answered. This is true if a green tick ✓ appears next to each page in the Section/Pages menu.



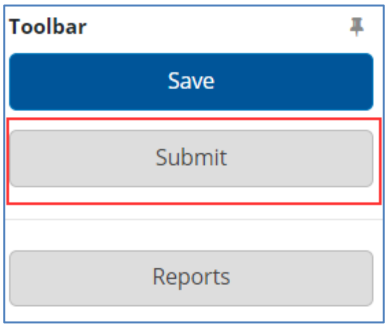
> ***Note:*** *If the page is not valid you will need to go to the page and complete all mandatory questions, fix any errors and click Save on the Toolbar.*

System guide to page indicators

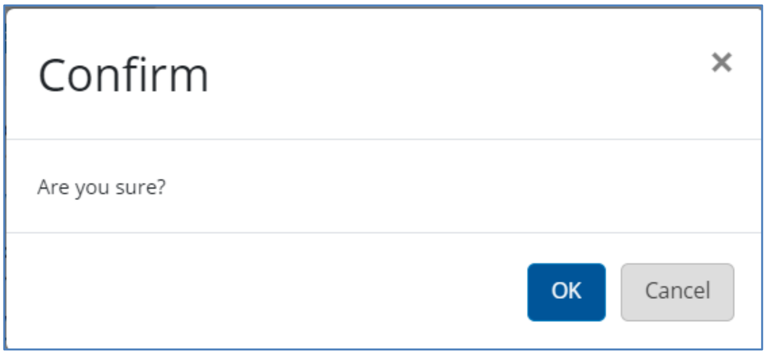
Indicator	Description
✓ Valid	All mandatory fields have been completed correctly. This will also display if you view a page with no mandatory questions, leave any or all fields blank, then move on.
‣ Unvisited	You haven't viewed the page yet so you need to go to it and complete the required fields. If you view the page but do not complete the details, the indicator will still disappear if there are no mandatory questions. Validation is not based on whether you complete the fields, just on if you go to the page. It may reappear, however, if you do not complete mandatory questions and in the warning popup you choose OK to continue and lose any data entered into the page. In this case, as no data is saved, the page is still considered "unvisited".
! Invalid	One or more fields on the page are not complete or not correctly completed, as highlighted in the page. Sometimes, this indicator may display when you create a new form, before you have visited a page. This happens when details are pre-populated. For example, your personnel details may be added to the form automatically but there may be associated mandatory fields that need to be completed.
? Revisit	A page that you had previously completed has new or changed elements that you need to review. Return to the page and complete any new questions or fields. If new fields are mandatory, they will be highlighted; if they are not mandatory, look for uncompleted fields. This may be because of an answer you gave to a different question in another page. For example, additional questions may be displayed in the previously completed page. This happens when there is a dependent relationship between questions, which is defined when the form is designed by your administrator.

When all pages are complete you are ready to submit the application.

Action: Click **Submit** on the Toolbar.



Result: A confirmation message will appear.



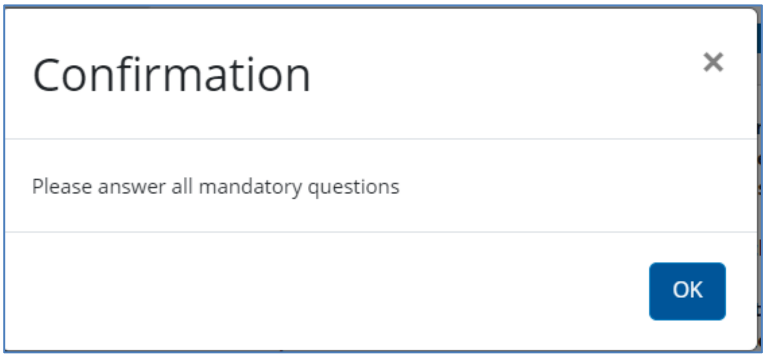
Action: Click **OK**.

Result: If the form is complete, the application is submitted to the next stage of review and the applicant is informed of the level of risk associated with the project. The Application Status and Workflow State will change accordingly.

Application is submitted by a student	Application is forwarded to the named Principal Supervisor Applicant will be informed of the risk associated with their research (Exempt, E1, E2 or E3)	Application Status changes from Draft to PS Review
Application submitted by staff is considered Exempt	Applicant is informed that the application has been determined to be 'Exempt Risk'.*	Application Status changes from Draft to Exempt
Application submitted by staff requires E1, E2 or E3 review	Applicant will be informed of the risk associated with their research (E1, E2 or E3)	Application Status changes from Draft to ECO Review

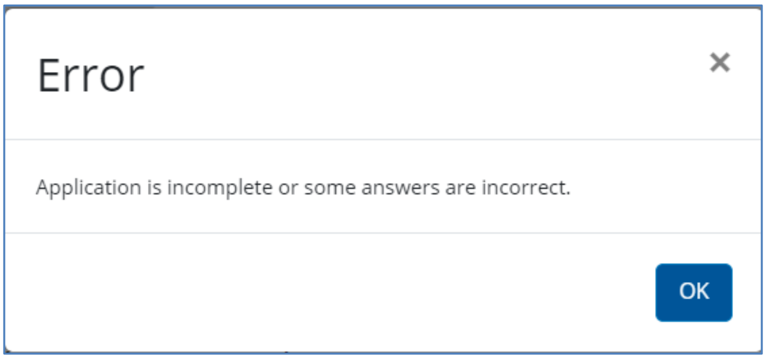
**__Note:__ The Human Research Ethics Officers will review applications that are submitted as Exempt to ensure that they meet the requirements for exemption from further ethical review. If the applicant has not completed the form correctly or exemption may not be appropriate, the applicant will be contacted by the Human Research Ethics Officer and asked to provide* *additional information in the online application.*

Result: If the form is incomplete, a second confirmation message will appear informing the applicant that their form cannot be submitted.



Action: Click **OK**.

Result: An error message will appear.



Action: Click **OK**.

Result: You are returned to the application to complete all questions as indicated by page indicators and error messages.

3. GENERATING APPLICATION AND COMMENTS REPORTS

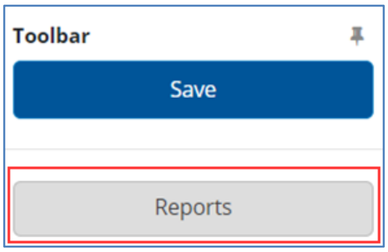
3.1 Generate a copy of the application

This function allows the applicant to generate a PDF or HTML copy of the application, enabling them to view all of their responses in the application in a single document as well as print or save a copy.

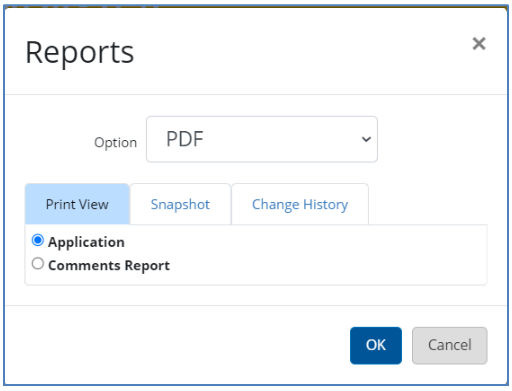
> ***Note:*** *A list of attached documents is included in the PDF or HTML copy of the application; however, the actual Attachments are not included in the PDF or HTML copy and must be opened separately.*

Navigation: Open the application.

Action: Click **Reports** on the Toolbar.



Result: The Reports panel will open.



Action: On the **Print View** tab, select **Application** and either **Option HTML** or **PDF**. Click **OK**.

Result: If PDF is selected, the document will download. If HTML is selected, the document will open in a new window.

> ***Note:*** *If the window does not open, check your Browser Settings to ensure that 'Pop Ups' are enabled.*

Action: Document can be printed or saved**.**

3.2 Generate a copy of the comments

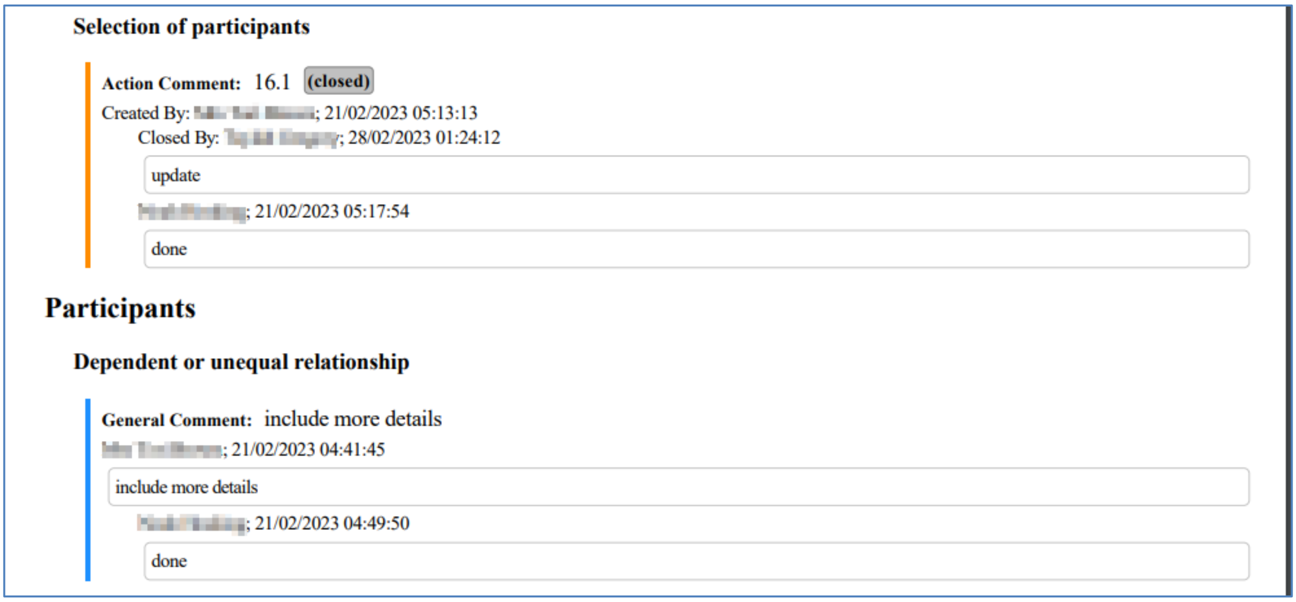
This function allows the applicant or reviewer to generate a PDF or HTML copy of the comments, enabling all comments to be viewed in a single document and printed or saved.

Action: Follow the steps in ***Section 3.1 Generate a copy of the application***, selecting the **Comments Report** option in the Print View tab.

About the new Comments Report in MyRM

- Section and Page headings are now included to show which page the comments are on.
- Each comment is captured in a thread or 'conversation'. It is now easier to see the original comment along with the subsequent response(s).
- Each comment will also include the name of the person who created the comment (as well as the date and time of comment creation), and where relevant the name of the person who closed the comment.
- Colour coded comment threads have been added, with a band of amber running down the left-

hand margin for Action Comment threads and a blue band for General Comment threads.



4. COMMENTS

4.1 Adding comments

The system allows comments to be added to each page of the application. General Comments can be used where necessary by applicants to provide further information to a page.

> ***Note:** Previously there were two types of comments – Form comments and Page comments. There are no longer any Form comments.*

> ***Note:** For existing applications that were created prior to the upgrade, any Form comments that had been added to the application will now be visible on the Create New Ethics Application page.*

Comments can also be added by the Principal Supervisor (if the applicant is a student) as part of their review of the application. Comments can also be added by those reviewing the application – the Human Research Ethics Officers, the Research Ethics Advisers allocated to review E2 applications and by the Chair/Deputy Chair(s) of the Human Research Ethics Committee. These reviewers can add Action Comments to indicate that the applicant needs to provide additional information or clarification about a particular question and/or page.

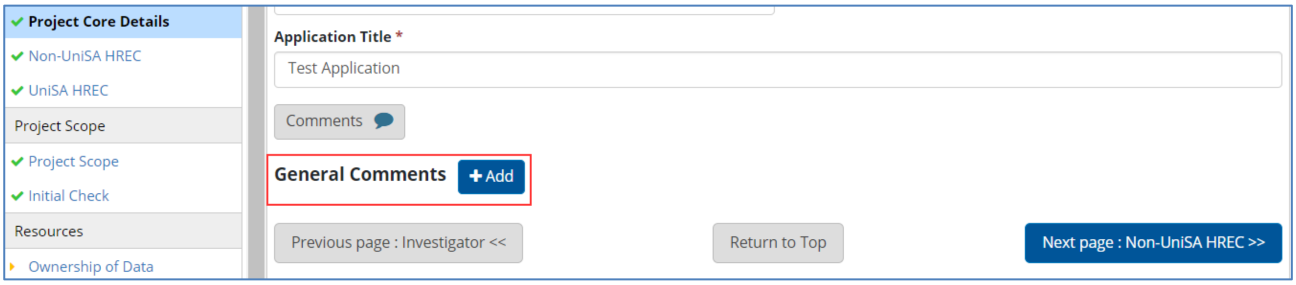
Comments added by the applicant or Principal Supervisor are visible to all Investigators listed on the application and the Ethics Reviewers.

4.1.1 To add a comment

Navigation: Go to the specific page within the application where you want to add a comment.

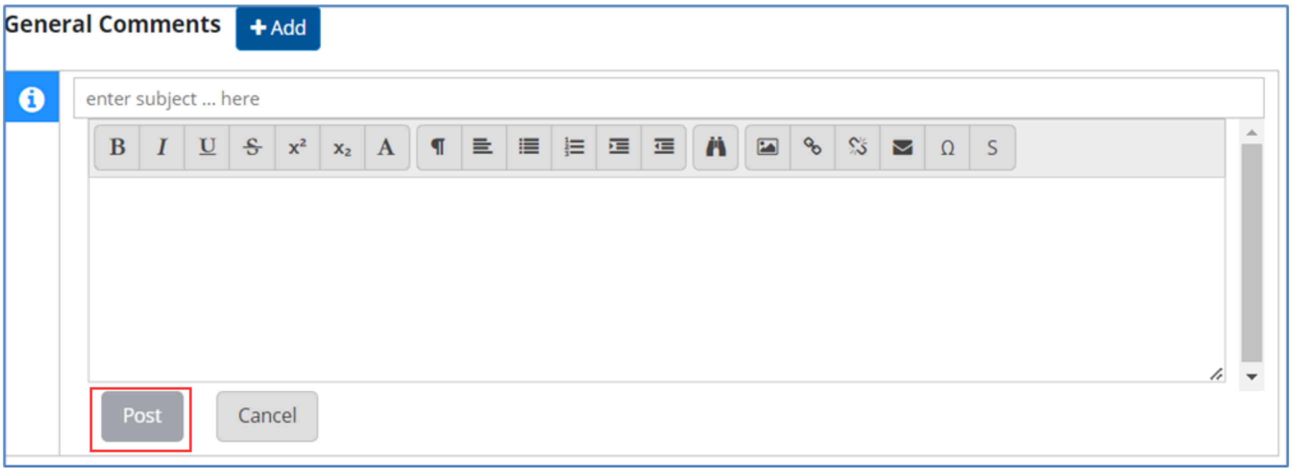
Action: Click on the **Comments button** below the questions.

Result: The **General Comments +Add** button appears.



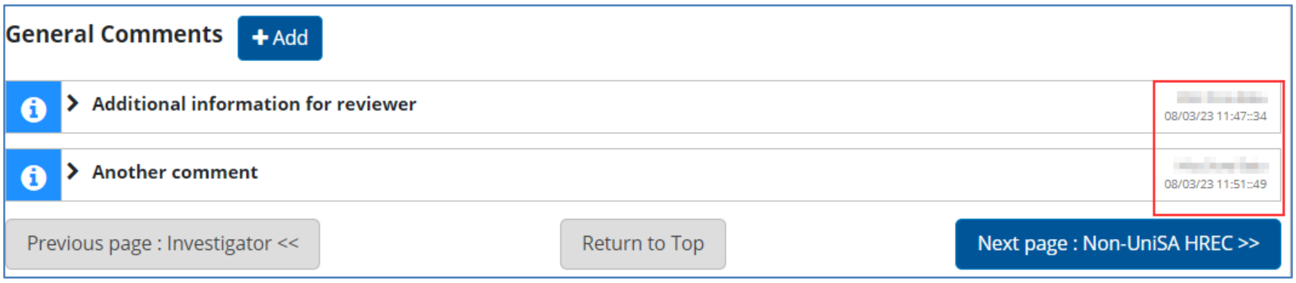
Action: Click **+Add.** Type the comment into the text box. Then click **Post** to save the comment to the page.

> ***Note:*** *You can 'Cancel' to delete the comment before you Post; however, once you have posted the comment you will need to re-open the comment and use the Delete button to remove the comment from the page.*

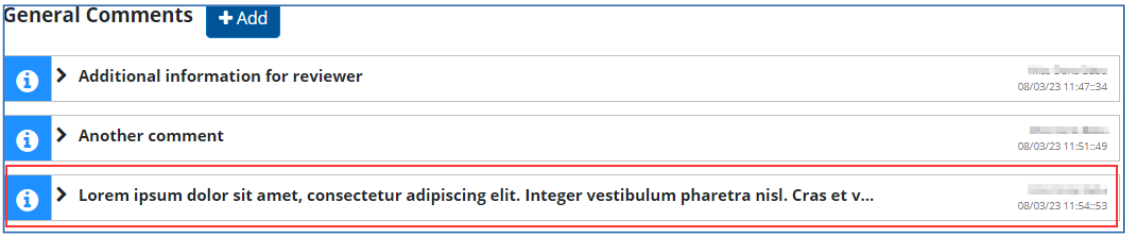


Result: The comment box will close and the new comment is saved and will appear below the +Add button. The name of the person that added the comment, with the date and time the comment was created will appear on the right-hand side of the subject line of the comment box.

Result: On the Sections/Page menu a blue comment bubble will be displayed to the right of the Page name.



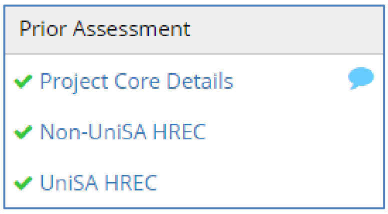
__Note__: A subject does not need to be added. However, the subject line will auto-populate from the content of the comment text box and default to the first 100 characters of the text box, so it is better to add a subject for ease of later reference and reading. The example below shows the subject line when a long paragraph is added to the comment text box.



Action: Repeat these steps to include additional comments on the application as needed.

4.1.2 How to identify pages with comments added

Pages that have comments added to them are indicated by a comment bubble on the Sections/Pages menu.

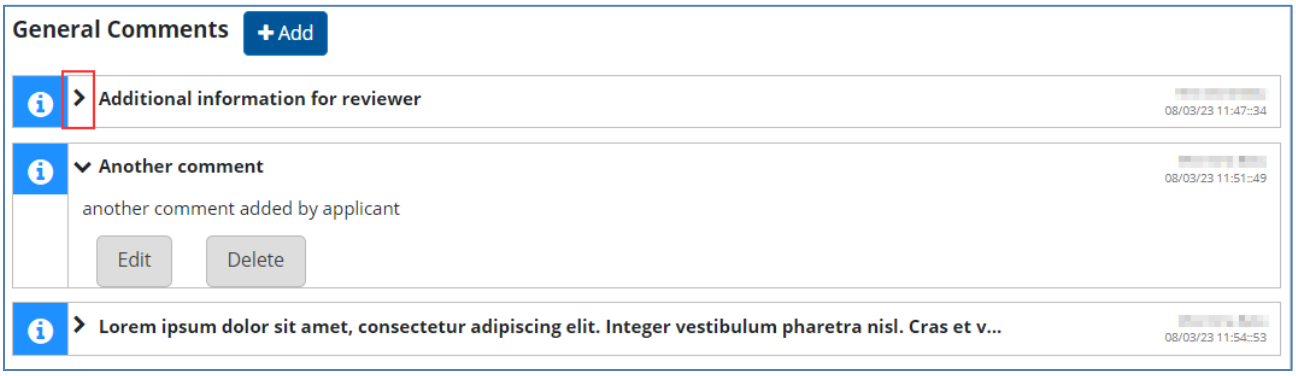


__Note__: Refer to Appendix 10.4 Comment Indicators for a description of each comment bubble

4.1.3 To edit a comment you have added

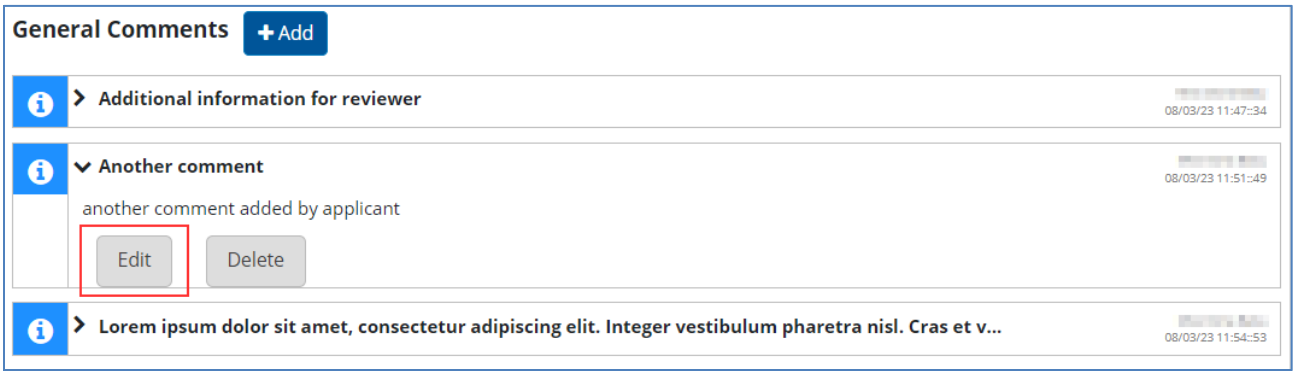
Navigation: Open the page within the application where the comment you wish to edit is located.

Action: Click on the **>** at the start of the Subject line of the comment.



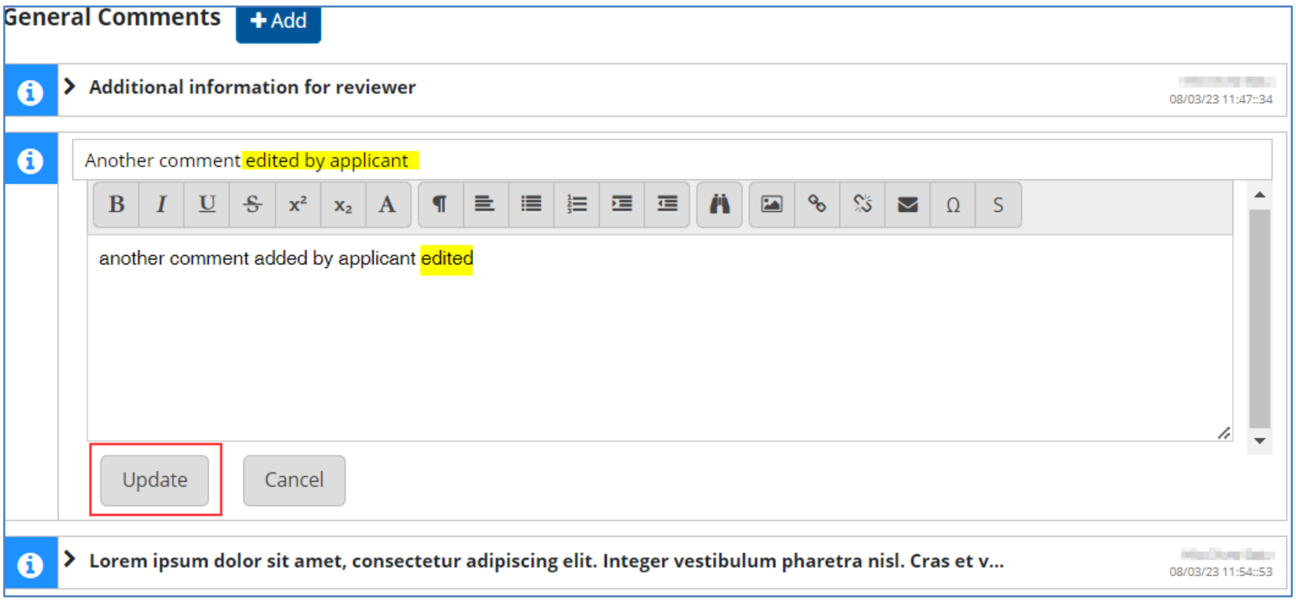
Result: The comment will open. An Edit button and Delete button are available.

Action: Click the **Edit** button.



Result: The Edit button changes to an **Update** button.

Action: Edit the text and/or subject line as needed. Click the **Update** button to save the changes.

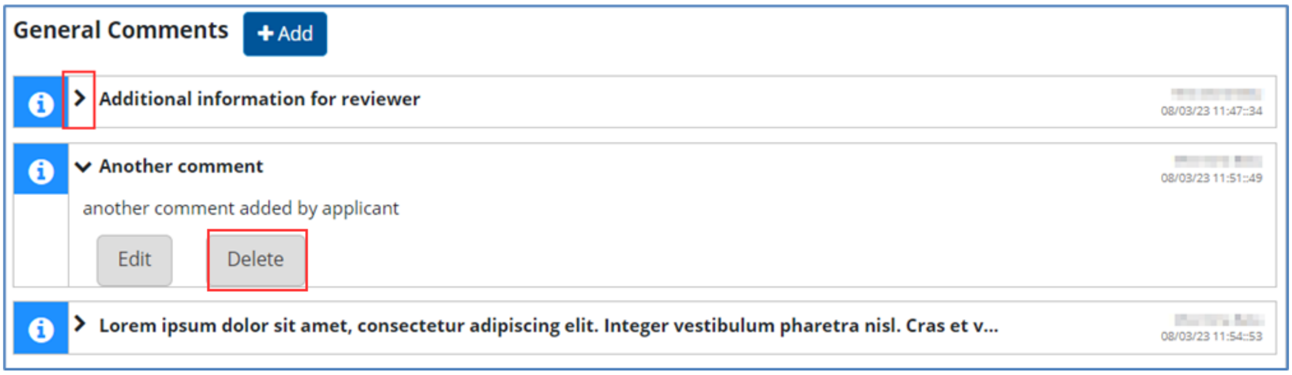


Result: The edited comment closes and appears in the comments list. The comment is updated.

4.2 Deleting comments

Navigation: Open the specific page within the application where the comment you wish to delete is located.

Action: Click on the **>** at the start of the Subject line of the comment to open the comment. Check you have the correct comment open. Click the Delete button on the comment you want to remove.



Result: The comment is deleted.

> ***Note**: There is no Undo Delete. If you delete a comment in error, you will need to add the comment again.*

> ***Note**: Prior to the upgrade a warning message displayed "This comment will be deleted. Do you want to continue?". This warning message does not currently display and will be reinstated by the vendor in a future update.*

5. REVIEWER'S COMMENTS

During the various stages of review, the application may be returned to the applicant with comments entered by the reviewer. You will receive an automated email notifying you that you are required to make changes to your application. When you log in to MyRM, you will see that an application returned to you with comments for attention will have one of the following Statuses:

- PS Update Required
- ECO Update Required
- Approved Subject To
- Not Approved: Resubmit

> ***Note**: PS stands for Principal Supervisor; ECO stands for Ethics & Compliance Officer (Human Research Ethics Officer)*

The process of responding to these comments is the same regardless of who wrote the comment. A reviewer can enter two types of comments:

Action Comments	Indicated as red comment bubbles on the Section/Pages menu	Require the applicant to make changes to their application and mark the item as 'responded' before they can resubmit the

		application.
General Comments	Indicated as blue comment bubbles on the Section/Pages menu	These comments do not necessarily require a response but should be viewed. There may be general notes or observations about the application added by the reviewer.

You may also see amber and green comment bubbles in the Section/Pages menu. When an Action comment has been responded to, the red comment bubble turns amber. When the response has been accepted by the reviewer the amber comment bubble turns green, as the action comment has been resolved.

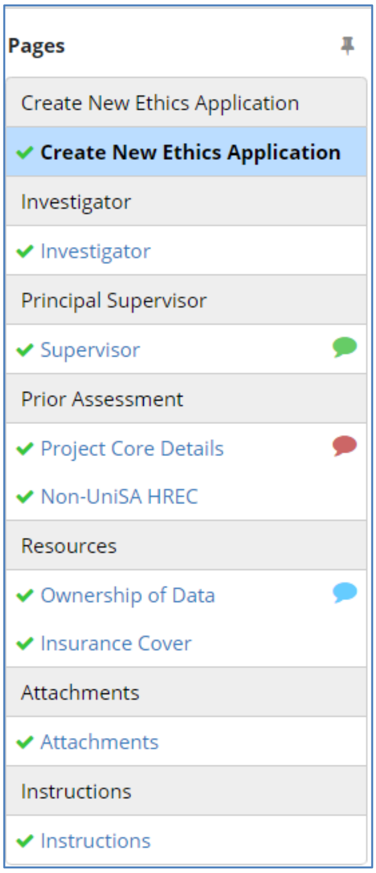
General Comments remain indicated by blue comment bubbles even if a response or conversation thread is included.

5.1 Responding to reviewer comments

Navigation: Select the relevant application from the list of your applications on the 'My Applications' tab.

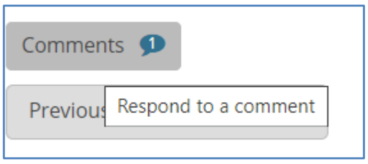
> ***Note**: Emails that are auto generated by the system include a link 'Application' which, when clicked, will take the user directly to the application form, removing the need to search for the relevant application after logging in.*

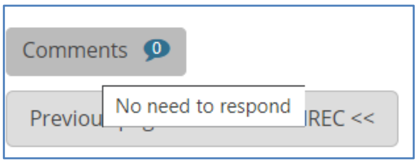
Action: Check for pages where comments have been added and open the first page with a comment that requires your attention (red or blue comment bubbles).



***Note**: If one or more Action Comments have been added to the page, the Comments button will display a number equivalent to the number of comments that require a response. If you hover the cursor over the Comments button the pop-up message 'Respond to a comment' will appear.*

If one or more General Comments have been added to the page, the Comments button will display the number '0' and the pop-up message upon hovering the mouse will indicate 'No need to respond'. You should read the comments even though you do not need to respond.





Action:

Option 1. Click the 'Expand All Comments' link at the top of the page (right hand side of page heading adjacent the Toolbar) to take you to the comments.

Option 2. Click the 'Page Comments n / n' link below the page heading to take you to the comments.

Option 3. Click on the Comments button at the bottom of the page.

Result: The comments that have been added by the reviewer are listed at the bottom of the page.

***Note**: Each comment will have an icon on the left-hand side of the subject line as another visual indicator.*

 *Action comment: Applicant action required*

 *Action comment: Applicant responded*

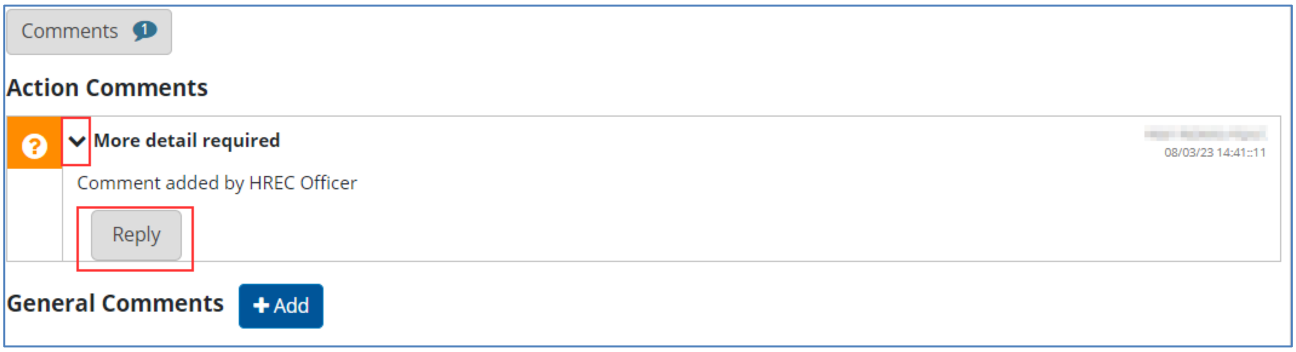
 *General comment*

 *View only – cannot edit or reply due to permissions or stage of workflow*

Action: Click on the **>** at the start of the Subject line of the comment to open the comment. Read the comment.

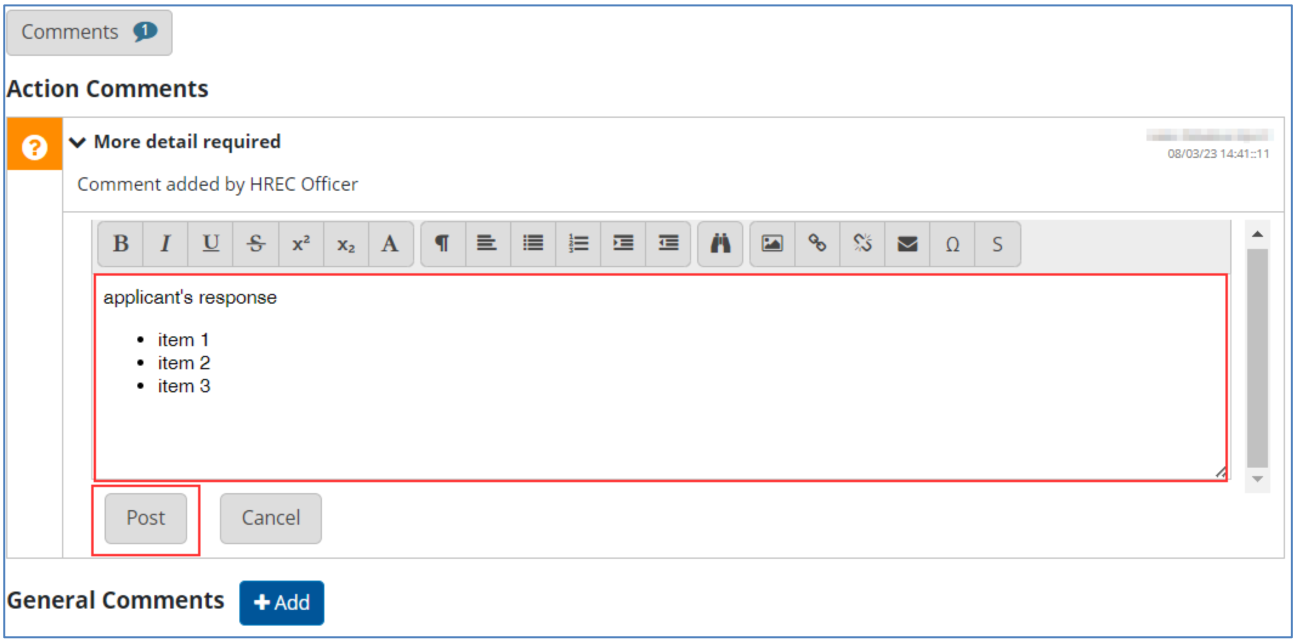
Once the review comment is read and understood, amend the application as necessary by making changes to your answers within the application and/or by revising the attached document(s). Once you have addressed the reviewer's comment, you will then need to respond to the Action Comment(s).

Action: To respond, click the **Reply** button.



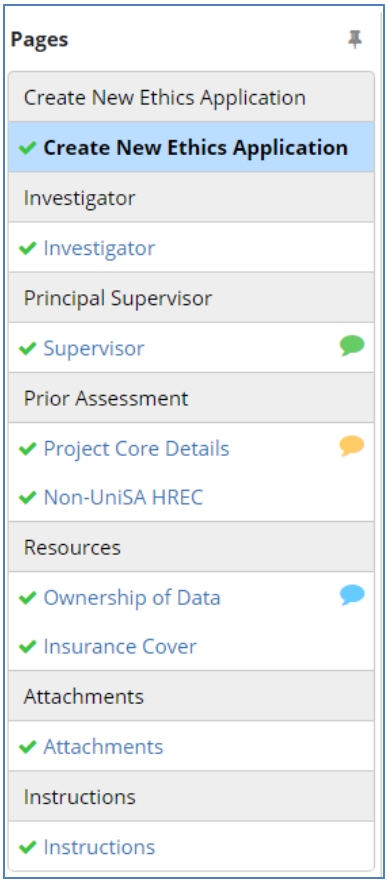
Result: A text box is revealed ready for your response to the Action Comment. The name of the person (Principal Supervisor, ECO or Ethics Reviewer) that posted the Action Comment will be displayed on the right-hand side of the comment subject line.

Action: Type your response in the text box, this may be a specific response to the comment or could be something as simple as "Done". Click the **Post** button to save your response.



Result: The response is posted. The red comment bubble on the Section/Pages menu has changed to an amber comment bubble. The icon on the comment has changed to green .

Continue navigating through the application pages, opening comments, amending the application as necessary by making changes to your answers within the application, revising the attached documents or adding your own page comments in response until there are no red comment bubble indicators on the Sections/Pages menu.



6. RE-SUBMITTING THE APPLICATION

An application can only be resubmitted once all Action Comments have been responded to and all red comment bubbles have turned to amber comment bubbles. An application cannot be resubmitted if there is a red comment bubble against any section.

Once all Action Comments and General Comments have been responded to, the application can be resubmitted by clicking the relevant action on the Toolbar.

7. EMAIL NOTIFICATIONS

Emails generated automatically by the system will be sent to the applicant, Principal Supervisor (if applicable) and Investigators listed on the application whenever the status of the application changes. Emails are also sent to the ECO and the Committee Review Group when their action is required.

The applicant cannot commence their research until they receive an email notifying them that final approval has been granted.

8. AMENDING AN APPROVED APPLICATION

Amendment requests are submitted and reviewed outside of the MyRM system.

Refer to the HREC FAQ ‘I need to deviate from the approved application – how do I tell HREC?’ at:

https://i.unisa.edu.au/staff/research/research-ethics/human-research-ethics/ethics-management-for-research-projects/

9. TROUBLESHOOTING

If you have difficulty accessing the online forms or MyRM in general, please contact the UniSA Research Office Systems Team on research.information@unisa.edu.au.

If you require ethics advice or guidance in relation to completing your application, please contact the relevant Research Ethics Advisor at: https://mymailunisaedu.sharepoint.com/teams/rch/ris/risethics/Pages/rea.aspx (login required) or refer to the HREC online system FAQs at: https://i.unisa.edu.au/staff/research/research-ethics/human-research-ethics/human-ethics-help-and-training/

For all other queries in relation to the Human Research Ethics application contact the Research Ethics and Compliance Team: Email: humanethics@unisa.edu.au, Tel: 8302 6330.

10. APPENDIX

10.1 APPLICATION STATUS

Term	Definition
Approved	The Committee Review Group has reviewed the application and is satisfied that the project meets the requirements of the *National Statement on Ethical Conduct in Human Research*. The applicant is approved to commence the research as outlined in the application.
Approved Subject To	The application has been reviewed by a Committee Review Group and returned to the applicant with the review outcome 'Approved Subject To'. The applicant is required to make minor changes to the application before resubmitting it for review and final approval.
Draft	An applicant has started an application. It has not yet been submitted.
E1 – HREC Chair	The Human Research Ethics Officer (ECO) has forwarded the application for review. At the time the application was submitted, the system checks determined that the research project does not pose a foreseeable risk of harm or discomfort, and any foreseeable risk is no more than inconvenience. The applicant was thus notified that the risk associated with the project requires E1 level of review. The application is forwarded to the Chair or Deputy Chair of HREC for E1 review. The Chair or Deputy Chair of HREC review E1 applications within 10 working days of receiving the application from the ECO.
E2 – Committee Group Review	The Human Research Ethics Officer (ECO) has forwarded the application for review. At the time the application was submitted, the system checks determined that the only foreseeable risk posed by the project is discomfort. The applicant was thus notified that the risk associated with the project requires E2 level of review. The application is forwarded to a panel comprising 2 members: The Chair or Deputy Chair of HREC and the applicant's Research Ethics Advisor. The review panel reviews E2 applications within 10 working days of receiving the application from the ECO.
E3 - HREC	The Human Research Ethics Officer (ECO) has forwarded the application for review. At the time the application was submitted, the system checks determined that the research project poses more than low risk. The applicant was thus notified that the risk associated with the project requires E3 level of review. HREC reviews E3 applications at their next meeting, held approximately every six weeks.
ECO Review	An applicant has completed an application and has submitted it to the Human Research Ethics Officer (ECO), who conducts an initial check for completeness and consistency.

10.1 APPLICATION STATUS

Term	**Definition**
ECO Update Required	The Human Research Ethics Officer (ECO) has reviewed the application and requires the applicant to provide additional information or amend answers provided.
Exempt	The applicant has submitted an application and the system check has determined that the research does not likely require further review as the project is: EITHER • negligible risk (i.e., no foreseeable risk of harm or discomfort, and any foreseeable risk is no more than inconvenience); and • involves the use of existing collections of data or records that contain only non-identifiable data about human beings. OR • conducted solely for the purpose of internal quality assurance and will not be published or presented externally; or • conducted solely for the purpose of internal quality assurance, and may be published externally only if the following criteria are met: • the data was gathered online or in writing • the responses were provided voluntarily • the respondents were advised of the possibility that the data could be used for such purposes; and • the anonymity of the respondents is maintained.
Negligible	Research projects in which there is no foreseeable risk of harm or discomfort, and any foreseeable risk is no more than inconvenience (and which are not exempt).
Not Approved	The Committee Review Group has reviewed the application and is not satisfied that the project meets the requirements of the *National Statement on Ethical Conduct in Human Research*, nor that it can meet the requirements of the *National Statement on Ethical Conduct in Human Research* if changes are made. The application is 'Not Approved' and cannot be resubmitted.
Not Approved: Resubmit	The Committee Review Group has reviewed the application and is not satisfied that the project meets the requirements of the *National Statement on Ethical Conduct in Human Research*, however it could meet requirements after significant changes are made. The review outcome is 'Not Approved: Resubmit'. The applicant is required to make significant changes to the application before resubmitting it for review.

10.1 APPLICATION STATUS

Term	Definition
PS Review	An applicant has completed an application and submitted the application for Principal Supervisor (PS) Review.
PS Review – ECO Update	Principal Supervisor (PS) to review changes made by the applicant, in response to the Human Research Ethics Officer's (ECO) comments.
PS Review – Review Update	Principal Supervisor (PS) to review changes made by the applicant, in response to the Review Group's (during E1, E2 or E3 review) comments.
Withdrawn	The Human Research Ethics Officer (ECO) has marked the application as withdrawn because: • the applicant has advised them that the research will not proceed; or • the application has been inactive for more than 6 months. It is not possible to 're-activate' a withdrawn application.

10.2 COMMON TERMS

Term	Definition
Committee Review Group	Refers to one of three review groups that assess human research ethics applications. They are: E1 – HREC Chair E2 – Review Panel E3 – Review by full Ethics Committee
ECO	Ethics and Compliance Officer
HREC	Human Research Ethics Committee
REA	Research Ethics Advisor
PS	Principal Supervisor

10.3 BUTTONS AND ICONS

Icon	Name	Description
Next page : Investigator >>	Next Page	Go to the next page in the application
Previous page : Project Scope <<	Previous Page	Go to the previous page in the application
Save	Save	Save the application
Comments	Comments	Comments that apply to a specific page
Reports	Reports	Reports menu to select and run a report, reports include the ability to print the whole application or the application comments
+ Add	Add	Add a page comment dialogue appears
	Help	Help for the page or for the question
Home > Ethics Applications Search > 205343: New Application	Exit	Click the breadcrumbs to exit the application and return to the Applications home page (Ethics Application Search) or the System Home page (Home)
✔ Project Core Details	Page complete	All questions have been responded to and page is complete
! Investigator	Page incomplete	There are errors or incomplete responses on the page. The page needs to be revisited and errors addressed.
▸ Attachments	Page not visited	The page has not yet been visited/opened.
? Project Scope	Page requires revisiting	Action on another page has caused a change to the page and so the page requires revisiting. If no error messages are visible, click Save on the Toolbar to clear the '?'

10.4 COMMENT INDICATORS	
Flag	Description
Red	A reviewer has entered an action comment on the page that requires action and/or response
Amber	The applicant has responded to the action comment
Green	The reviewer has resolved and closed the action comment
Blue	There is a general comment on the page or application. This should be read, but no action is required.