University of
South Australia

User Guide

Human Research Ethics Applications

My Research Management (MyRM)

Supervisor Guide
Version 5

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

Contents

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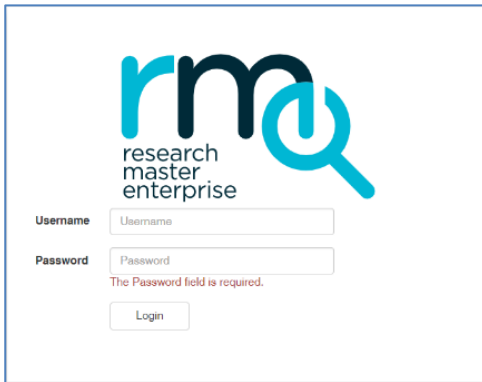
The University's Human Research Ethics webpage provides further information on the ethics application and review process: https://www.unisa.edu.au/research/integrity/research-ethics/human-ethics/

> *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 Applications for review

For Human Research Ethics applications where the Applicant is a **student** they are 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.

> *Note: If an application is not visible in the list of applications you may need to check with the student to ensure that they have added you correctly to the application on the Principal Supervisor page (particularly if you also have a student ID or an external ID as well as a staff ID).*

As Principal Supervisor, you will thus receive an automated email notifying you that an application is ready for your review. Applications ready for your review will be in the status **PS Review.**
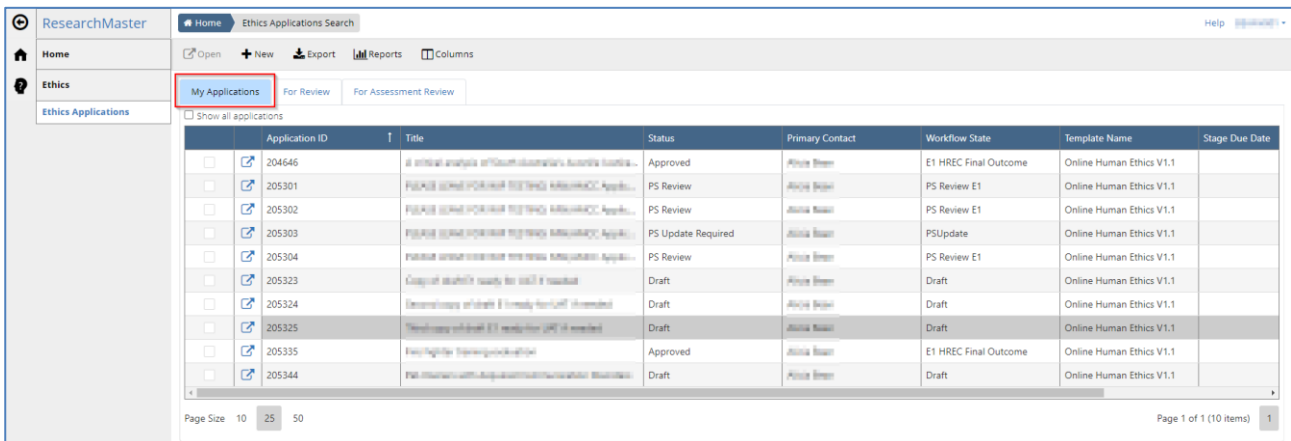
> *Note: Emails that are auto generated by the system include a link 'Application' which, when clicked, will take the user directly to the application form, removing the need to search for the relevant application after logging in (i.e. clicking the link instead of the Steps at 1.2.1 below).*

1.2.1   Locating applications for review

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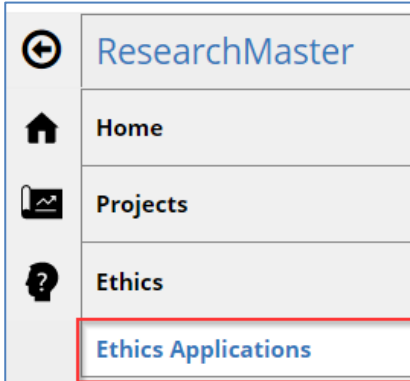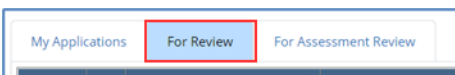

Result: The Ethics Applications page opens and the 'My Applications' tab is activated. Applications available to the user are displayed.

Action: Click the For Review tab.

Result: The **For Review** tab is activated and the application should be listed.

> *Note: The application will be forwarded to all Supervisors listed on the application by the student. However, only the Principal Supervisor should formally review the application. If you have received an application in error, click **Revert** on the Toolbar to send the application back to the Student and ask them to change the Supervisor (refer to the User Guide: Applicant Guide).*

2. REVIEWING THE APPLICATION

2.1 Navigating the application

There are **four components** to the application.
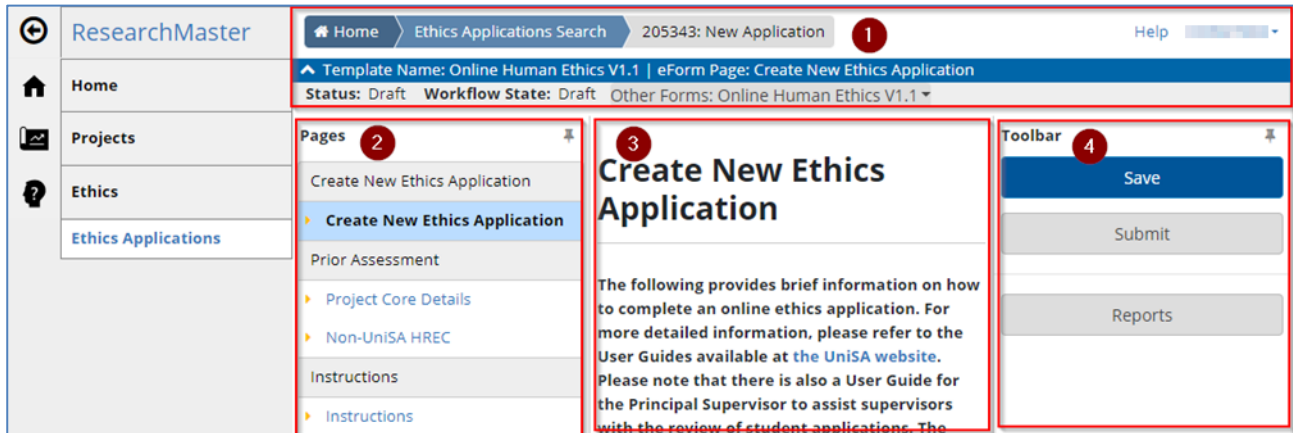
❶ **eForm Header:** Located at the top of the screen, the eForm Header displays:
   a) the breadcrumbs (Home > Ethics Application Search> Ethics Application ID: Ethics Application Title);
   b) Help menu;
   c) User Session (note, user name is blurred in this image). Click your user name to find the 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.

④ **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	Viewing attachments

The Attachments section allows the student to upload documents to support their application. This includes, but is not limited to:
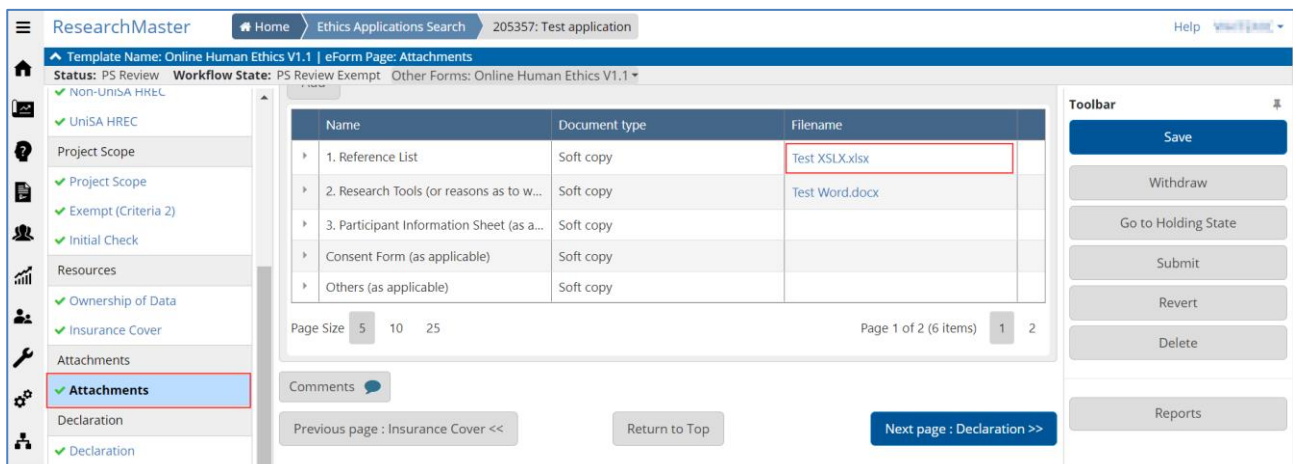
- A list of key references
- The research tools:
    - Questionnaire(s)
    - Interview/focus group questions or topics
- The recruitment material:
    - Participant Information sheet(s)
    - Participant Consent form(s)
    - Recruitment flyer(s) / letter(s)
    - Scripts for recruitment telephone calls
- 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. Applicants can add their 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.

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.*
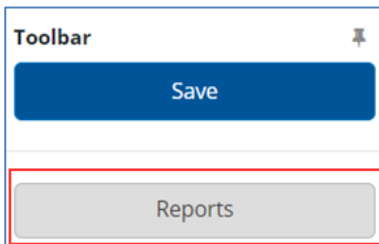
3. GENERATING APPLICATION AND COMMENTS REPORTS

3.1 Generate a copy of the application

This function allows the applicant or reviewer to generate a PDF or HTML copy of the application, enabling them to view all of the 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.
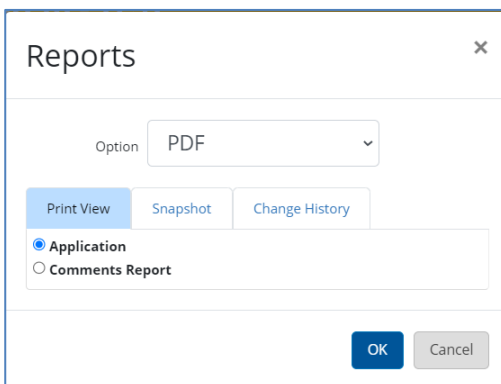
Action: On the **Print View tab**, select **Application** and either **Option HTML** or **PDF**. Click **OK**.

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

- o Section and Page headings are now included to show which page the comments are on.
- o Each comment is captured in a thread or 'conversation'. It is now easier to see the original comment along with the subsequent response(s).
- o 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.
- o 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

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.

As a reviewer, the Principal Supervisor can add 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.

Depending upon the stage of the workflow, 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.
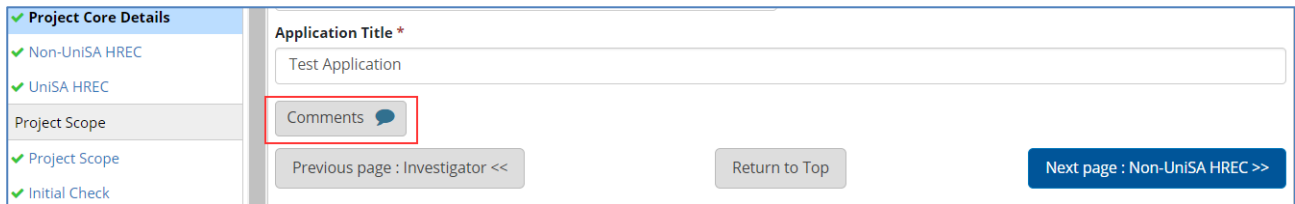
Note: A 4000 character limit applies to each 'comments' field.

4.1   Adding comments

4.1.1   To add a comment

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

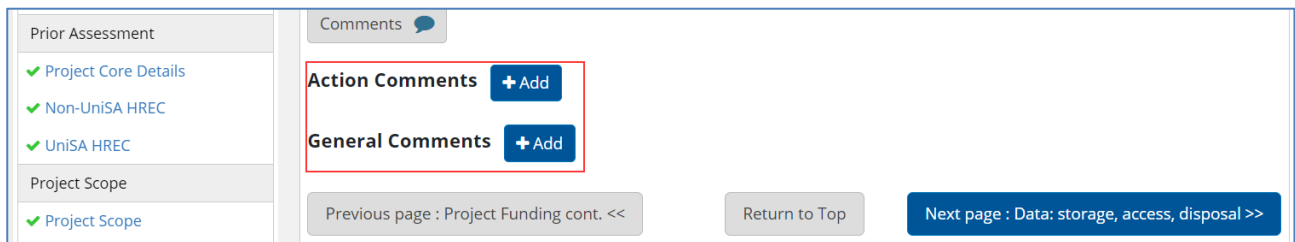**Action:** Click on the **Comments button** below the questions.

University of
South Australia

Application Title *

Test Application

Comments 💬

Previous page : Investigator <<   Return to Top   Next page : Non-UniSA HREC >>

✔ Project Core Details
✔ Non-UniSA HREC
✔ UniSA HREC
Project Scope
✔ Project Scope
✔ Initial Check

Result: The **Action Comments +Add** and the **General Comments +Add** buttons appear.

Prior Assessment
✔ Project Core Details
✔ Non-UniSA HREC
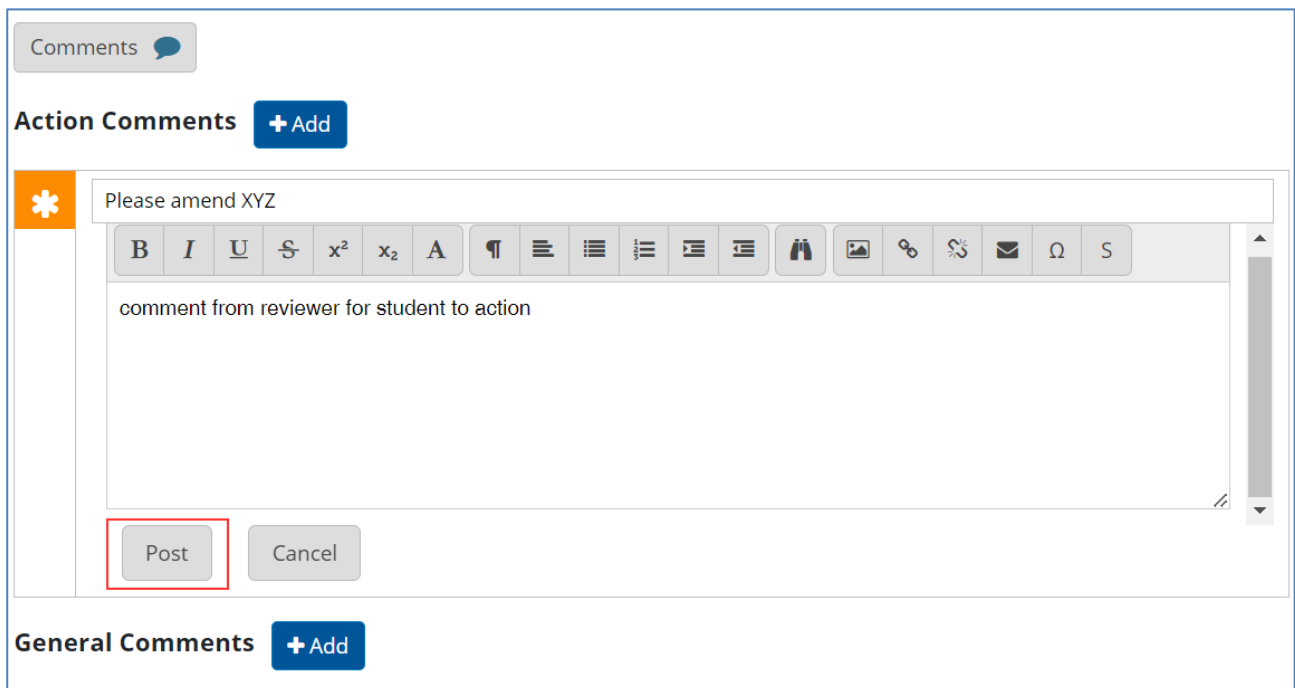✔ UniSA HREC
Project Scope
✔ Project Scope

Comments 💬

Action Comments + Add

General Comments + Add

Previous page : Project Funding cont. <<   Return to Top   Next page : Data: storage, access, disposal >>

Action: Click **+Add** for the type of comment you wish to add. Type the comment into the text box. Then click **Post** to save the comment to the page.

> *Note:* Select 'General Comments' if you do not require an immediate action or response from the applicant. Select 'Action Comment' if you require a response from the applicant in order for the student to resubmit the application.

> *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.

Comments 💬

Action Comments + Add

Please amend XYZ

B I U S x² x₂ A ¶ ≡ ☰ ≣ ⇥ ⇤ 🔍 🖼 🔗 🔊 ✉ Ω S

comment from reviewer for student to action

Post   Cancel

General Comments + Add

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.
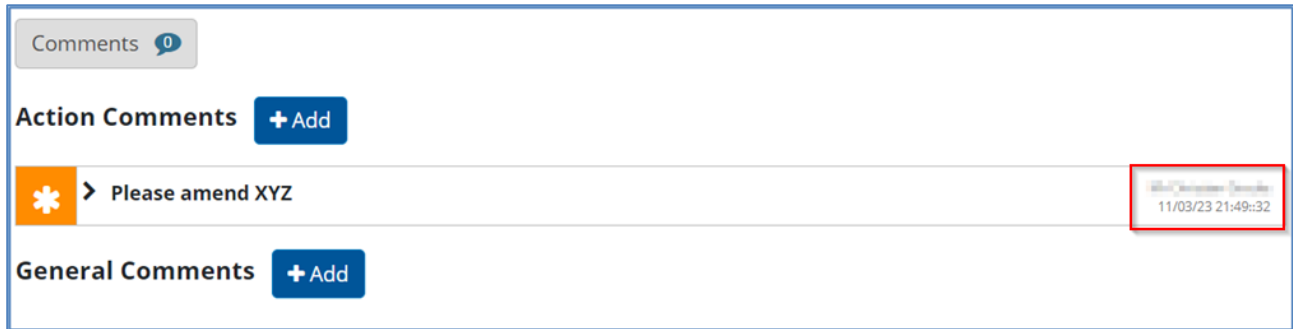
Note: *A subject does not need to be added. However, the subject line will auto-populate from the content of the comment box and default to the first 100 characters of the text box, so it is better to add a subject for ease of later reference and reading. The example below shows the subject line when a long paragraph is added to the comment text box.*
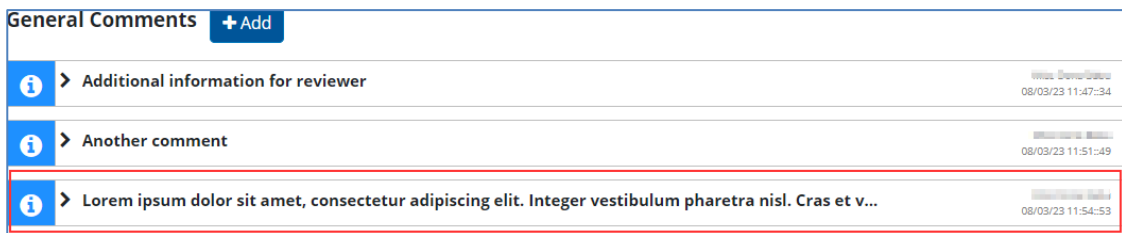
Action: Repeat these steps to include additional comments on the application as needed.

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

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.
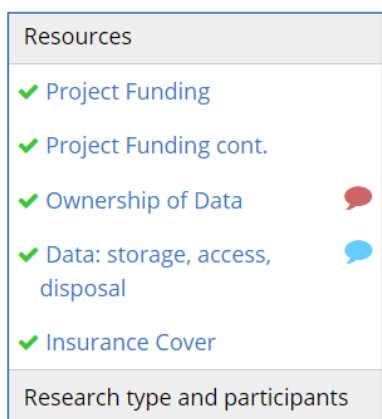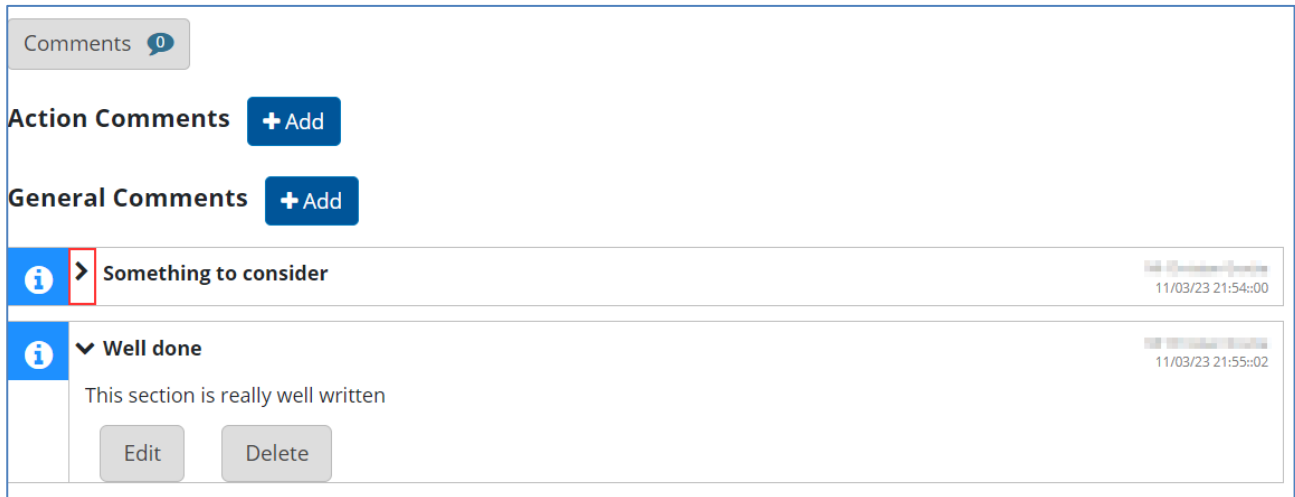
Note: *Refer to Appendix 9.4 Comment Indicators for a description of each comment bubble*

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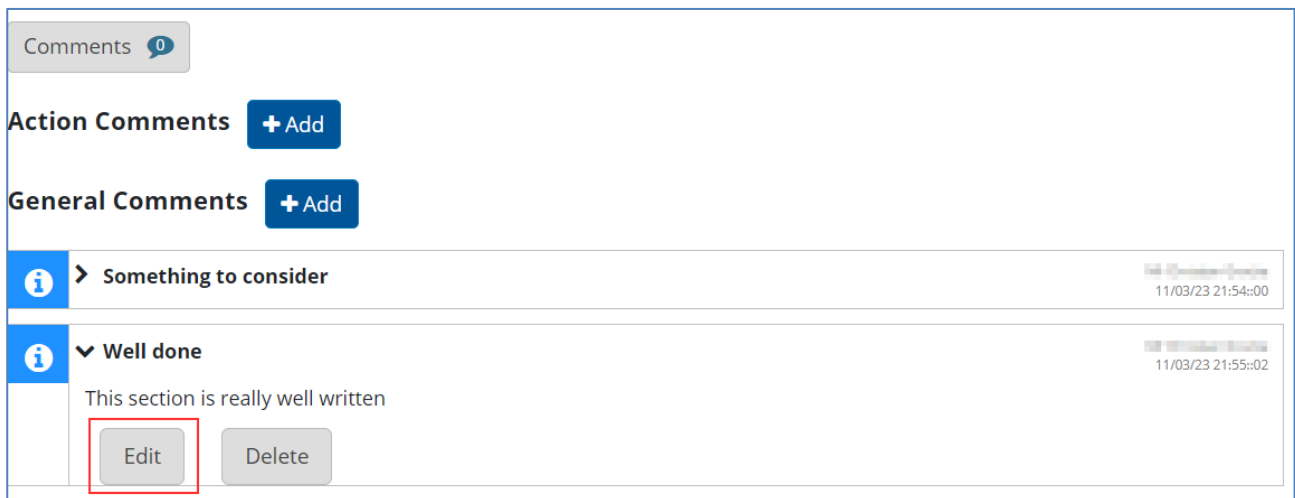
Action: Click on the **>** at the start of the Subject line of the comment.

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.

| ⓘ | > Something to consider | 11/03/23 21:54::00 |

| ⓘ | Well done |

B *I* U S x² x₂ A ¶ ≡ ≣ ≣ ≣ ≣ 🔍 🖼 🔗 ✂ ✉ Ω S

This section is really well written and you have addressed all of the matters we discussed.

[Update] [Cancel]
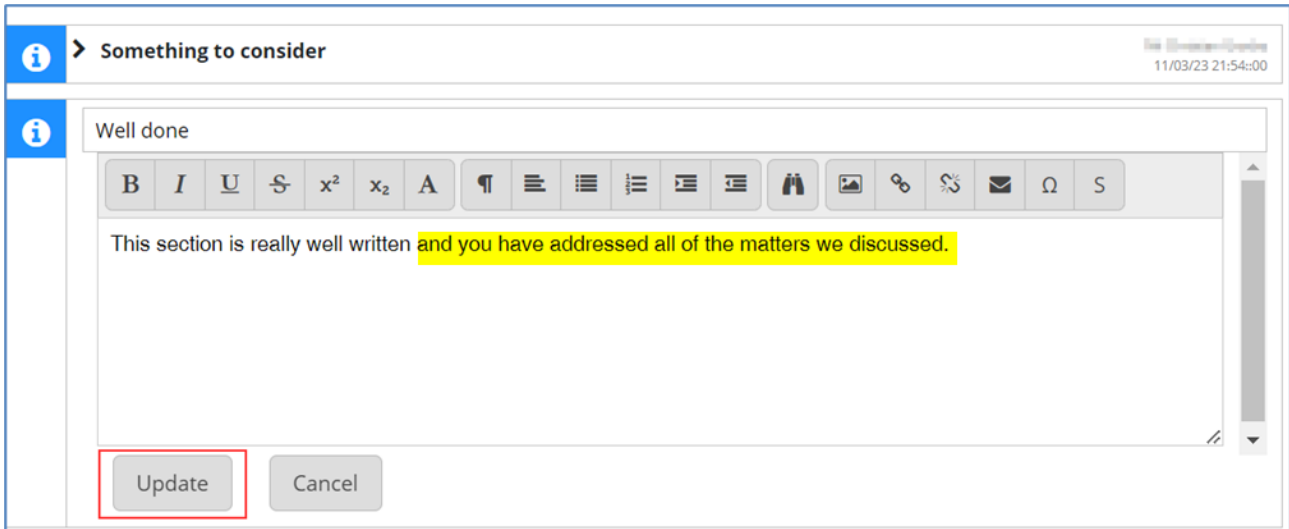
Result: The edited comment closes and appears in the comments list. The comment is updated.

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.

General Comments **+ Add**

| ⓘ | > Additional information for reviewer | 08/03/23 11:47::34 |

| ⓘ | ∨ Another comment | 08/03/23 11:51::49 |

another comment added by applicant

[Edit] [Delete]

| ⓘ | > Lorem ipsum dolor sit amet, consectetur adipiscing elit. Integer vestibulum pharetra nisl. Cras et v... | 08/03/23 11:54::53 |
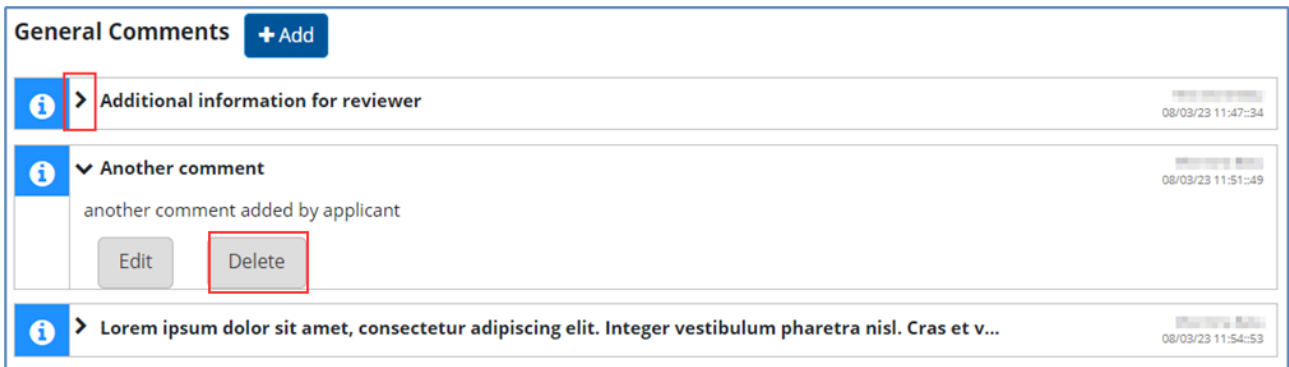
Result: The comment is deleted.

> **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.*

4.3   Reviewing responses to comments

Once the student has amended the application according to the Supervisor's comments and re-submitted it for review, the Principal Supervisor must check whether the student has satisfactorily responded to the requirements. If all matters have been addressed satisfactorily, the Principal Supervisor must Close all Action Comments before submitting the application to the Human Research Ethics Officer (ECO)

Action Comments that you have added in your earlier review will appear as amber 💬 comment bubbles in the Section/Pages menu, indicating that the student has responded to the comment and that it now requires checking by the Principal Supervisor accordingly.

If you added General Comments in your earlier review they will remain blue even if a response has been added by the student.

> *Note: Principal Supervisors only need to Close their own comments – they do not need to close off comments that are provided by the Human Research Ethics Officer (ECO). Principal Supervisors are encouraged to check that these comments have been actioned by the student, but they should leave the amber 💬 comment bubbles so that the ECO can review and Close their comments accordingly.*

If the comments added by the Principal Supervisor in their earlier review have not been addressed adequately by the Student, more comments should be added and the application must be sent back to the student for further changes.
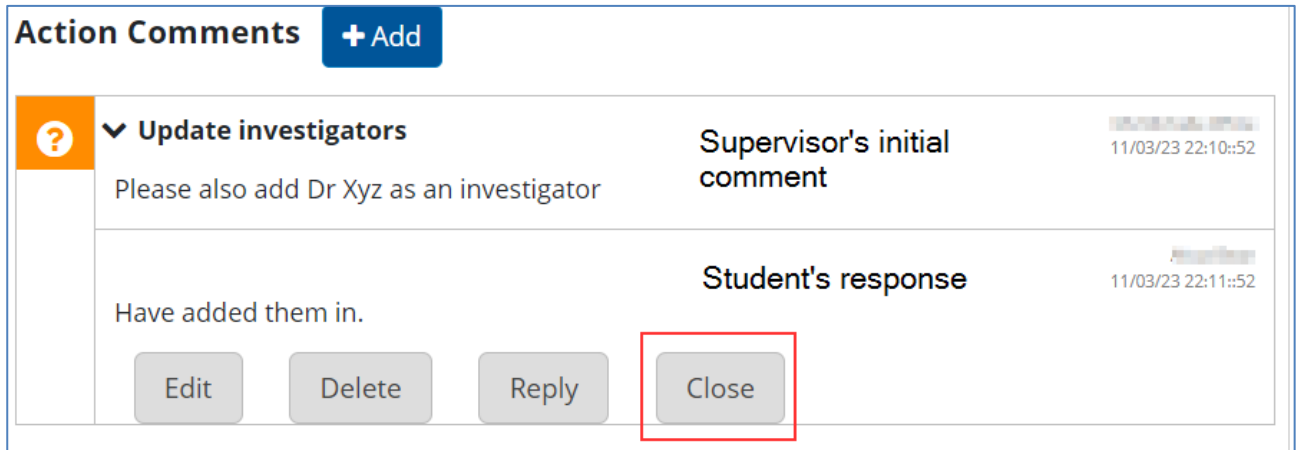
4.3.1   To close a comment

Action: Check in the Sections/Pages menu for pages where comments have been added and open the first page with a comment that requires your attention (amber or blue comment bubbles).
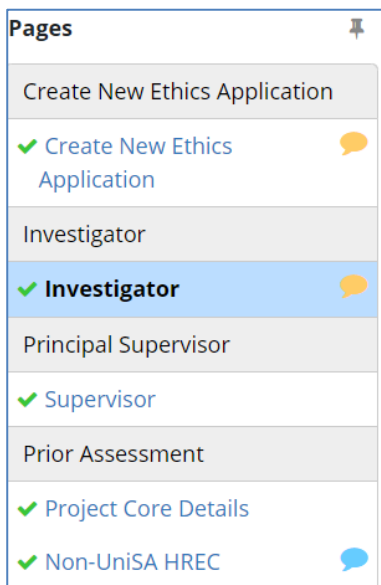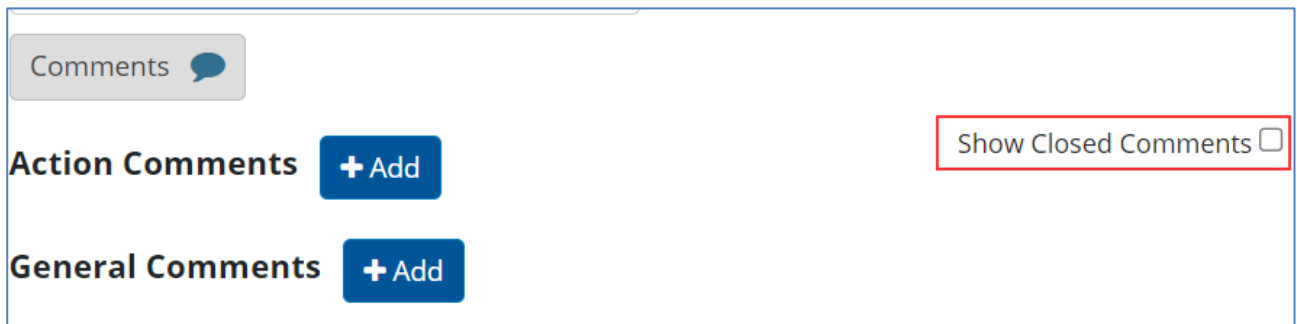
Action: Click on the **>** at the start of the Subject line of the comment to open the comment. Read the comment response from the student. Confirm that required changes to the question(s)/page have been completed.

Action: Once satisfied that the Action Comment has been adequately addressed, select **Close**.
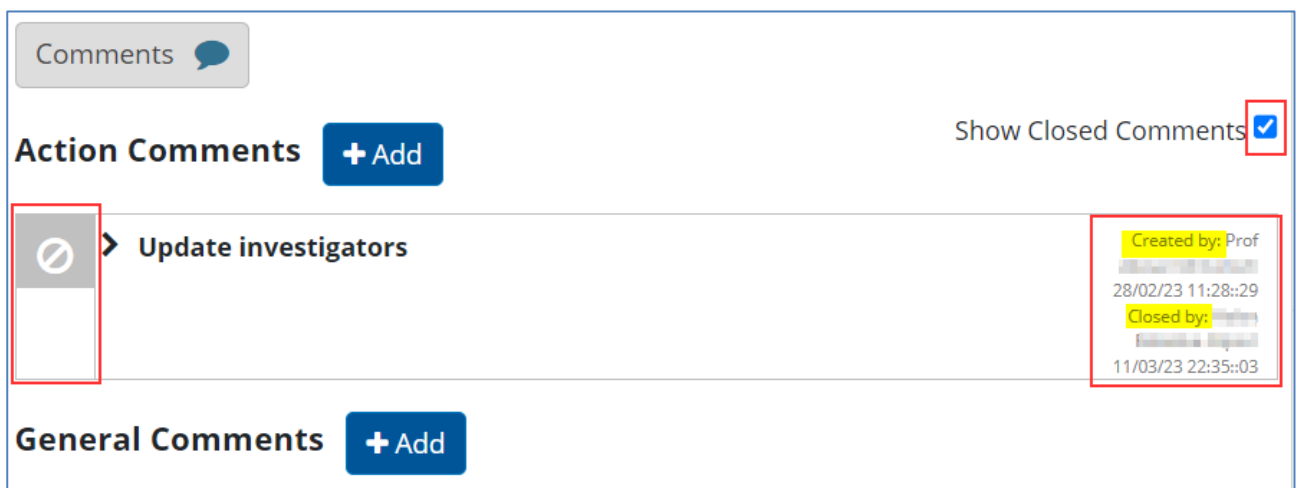
Result: The comment box will close. The comment will also disappear from the page and a 'Show Closed Comments' tick box will become visible. The amber 💬 comment bubble on the Section/pages menu has changed to a green 💬 comment bubble.

4.3.2   To see closed comments

Action: Tick the 'Show Closed Comments' tick box.

Result: Closed comment(s) will appear.

5.   SUBMITTING/REVERTING APPLICATION

Once the Supervisor has reviewed the full application and attachments, they can either revert the application back to the student if changes are required or submit the application to the Human Research Ethics Officer for further review.

5.1   Reverting the application

Action: Click **Revert** on the Toolbar.
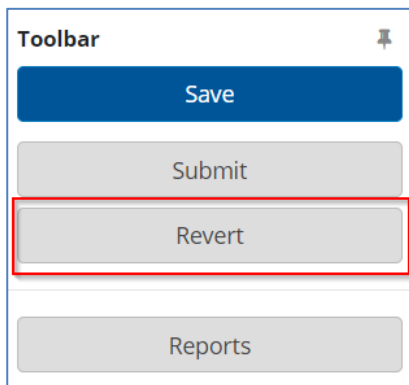
Result: A confirmation message "Application sent to applicant for further changes" appears.

Action: Click **OK**.

> *Note: If all Action Comments have not been resolved (all comment bubbles on the Section/Pages menu are green or blue if resolved/closed; Action Comments display amber comment bubbles if not yet closed) then a confirmation message "Please resolve all comments" will appear. Click OK. Review and close all comments, then click Revert on the Toolbar again.*

Result: The application Status updates to **PS Update Required**. The application has been sent back to the student so that they can make the necessary amendments. An email is sent to alert the student that they need to login and review the supervisor's comments.

5.2   Submitting the application

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

Result: A confirmation message "Application forwarded to ECO" appears.

Action: Click **OK**.

> *Note: If all Action Comments have not been resolved (all comment bubbles on the Section/Pages menu are green or blue if resolved/closed; Action Comments display amber comment bubbles if not yet closed) then a confirmation message "Please resolve all comments" will appear. Click OK. Review and close all comments, then click Submit on the Toolbar again.*

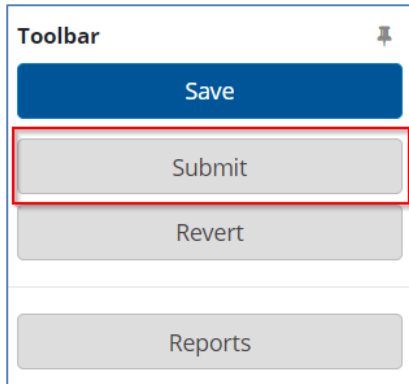**Result:** The application Status updates to **Exempt** or **ECO Review**. An email is sent to advise all investigators of the change in status.

6.   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.

7.   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/

8.   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).

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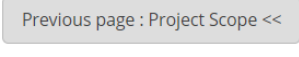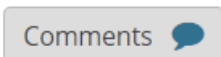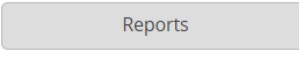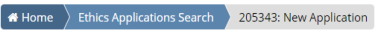
9. APPENDIX

9.1 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.

9.1 APPLICATION STATUS

Term	Definition
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.
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

9.1   APPLICATION STATUS

Term	Definition
	outcome is 'Not Approved: Resubmit'. The applicant is required to make significant changes to the application before resubmitting it for review.
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.

9.2 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 Human Research Ethics Committee (HREC)
ECO	Human Research Ethics Officer
HREC	Human Research Ethics Committee
REA	Research Ethics Advisor
PS	Principal Supervisor

9.3 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, application comments, attached documents and review outcomes
➕ Add	Add	Add a page comment dialogue appears
❓	Help	Help for the page or for the questions
🏠 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 '?'

9.4	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 note on the page or application. This should be read, but no action is required.	