



University of South Australia

User Guide

Human Research Ethics Application and Review System

Principal Supervisor Guide

Version 2

Research and Innovation Services

For further information or assistance please contact the Research Ethics Office:
e-mail humanethics@unisa.edu.au, ph. 830 23723

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University of South Australia

OVERVIEW: HUMAN RESEARCH ETHICS APPLICATION AND REVIEW SYSTEM

All staff and students at the University of South Australia (UniSA) 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 UniSA Human Research Ethics Committee (HREC) using the Human Research Ethics Application and Review System (the System).

Researchers must be familiar with the following documents before using the System:

- a. the *National Statement on Ethical Conduct in Human Research* (http://www.nhmrc.gov.au/publications/synopses/_files/e72.pdf),
- b. the *Australian Code for the Responsible Conduct of Research* http://www.nhmrc.gov.au/publications/synopses/_files/r39.pdf,
- c. related legislation, guidelines and codes, and University policies and procedures as outlined in the University of South Australia's Framework for the Responsible Conduct of Research (<http://www.unisa.edu.au/res/ethics/integrity/default.asp>).

The University's Human Research Ethics webpage provides further information on the ethics review process: <http://w3.unisa.edu.au/res/ethics/human/default.asp>

Note: The images displayed in this user guide were captured using fictitious examples of a human ethics Application and do not contain information or details of actual Applications.



University of South Australia

GETTING STARTED

Step 1: Logging In

Navigation:

<https://research.unisa.edu.au/RMENet/>

University of South Australia
UniSA

ResearchMaster Enterprise: 5.12.1

User Name: Password: Log In

Welcome to RMENET at ResearchMaster

Welcome to the Research & Innovation system for tracking, processing and administering research management in the University.

To login, enter your username and password in the fields provided and then click the Log In button. If your username has been validated correctly, you will be taken to the RMENET Home page.

Disclaimer | Copyright | Privacy | Australian Technology Network | Web accessibility | CRICOS Provider no 90121B | Contact UniSA | H0M000116

Copyright © 2012 ResearchMaster Pty Ltd

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

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



Step 2: Applications for Review

Navigation:

Ethics Tab→Applications

University of South Australia
UniSA

ResearchMaster Enterprise: 5.12.1

Home Ethics Personnel Help

Home Applications

Disclaimer | Copyright | Privacy | Australian Technology Network | Web accessibility | CRICOS Provider no 00121B | Contact UniSA

Action: Click on **My Applications** or **All Applications**.

Result: Applications available for review are displayed.

Note: Applications are grouped according to their status.

Type	Application ID	Application Title	Status	Primary Investigator	Process Stage	Template Name	Application Date
HUMAN	0000029236	Test Student Application	PS Review	Mr Vaneet Vaneet	PS Review E2	Ethics Protocol	N/A

Action: Click on the **Application Title** to open the application.

Result: The **Application** is displayed

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, **revert** the Application back to the Student Application and ask them to change the Supervisor (see [Reverting the Application](#)).

Test Student Application

Application Status: PS Review Workflow State: PS Review E2 Other Forms: Ethics Protocol

Form Action

Create New Ethics Application

Create New Ethics Application

Investigator

Principal Supervisor

Prior Assessment

Project Details

The following provides brief information on how to complete an online ethics application. For more detailed information, please refer to the User Guides available at the UniSA website. Please note that there is also a UI Guide for the Principal Supervisor to assist supervisors with the review of student applications. The User Guides also detail the process to follow should you be required to respond to reviewers comments.

The System allows researchers to complete and submit human ethics applications electronically. Applicants navigate their way through the application by answering a number of questions. Sections, pages and / or questions appear based on the answers to previous questions therefore it is advisable that you complete questions sequentially in order to avoid skipping questions unintentionally. At times, word limits may prevent you 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 (function available on the left hand menu available the Attachments Section), or as a page comment. Please refer to the User Guides if you are unsure how to use these functions.

Please ensure you enter requested information in the sections available on the screen's left hand menu (Investigators, Attachments etc). Submitted applications that do not contain the required information will be return you and therefore the review process will be delayed. Refer to the User Guides if you are unsure how to use these functions.

ANSWERING QUESTIONS

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 syntax errors.

Student applicants: Please note that you must email your supervisor a copy of all attachments included in your application.

A The research activity must not commence until ethics approval is finalised *

☐ I agree



REVIEWING THE APPLICATION

Step 1: Navigating the Application

Navigation:

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

1. **Information Area:** Located at the top of the screen, the Information Area displays the Application Title, Status, Current Workflow State and the Current Ethics Form.

Test Application

Application Status: PS Review Workflow State: PS Review E2 Other Forms: Ethics Protocol

2. **Toolbar:** Located in the top right hand corner of the application, the Toolbar provides actions available to view and review the application. Icon descriptions can be found in the [Toolbar Appendix](#).



3. **Application Navigation:** Located on the left hand side of the application, the Navigation section provides easy access to sections within the application (**Form** tab), and available actions (**Action** tab).

4. **Application Content:** The main section of the screen, displays the application questions and responses.



Step 2: Viewing Investigators

Navigation:

Click the *Investigator* page under the *Investigator* section.

Test Student Application

Application Status: PS Review Workflow State: PS Review E2 Other Forms: Ethics Protocol

Form Action

Expand » Collapse «

- Create New Ethics Application
- Create New Ethics Application
- Investigator**
- Principal Supervisor
- Prior Assessment
- Project Details
- Ethics Training
- Project Type
- Project Details
- Project Dates
- Resources
- Project Funding

Investigator

1 Is primary applicant a student? Please select 'Yes' if you are a student; if you are a staff member answer 'No' *

☒ Yes

☐ No

2 Please edit the investigator section by marking the primary applicant as "Primary"
(Please click on the name and then select 'Yes' to 'Primary')

After making the selection, please 'save' it by clicking on the green tick at the right hand side bottom corner.

Please include all other investigators on this page by using the search function and mark the role as 'Other Investigator' from the drop down box .

After making the selection, please 'save' it by clicking on the green tick at the right hand side bottom corner.

ID	Given Name	Surname	Full Name	Primary?	Position	AOU	Organisation	Organisation Name
100111743	Vaneet	Vaneet	Mr Vaneet Vaneet	Yes	Chief Investigator	MGN		

3 Have you made the necessary changes required by marking the applicant as 'Primary'? Please make the changes to avoid any inconvenience and respond with 'Yes' . *

☒ Yes

☐ No

Action: Click the **Full Name** of the investigator.

Result: Additional information about the investigator is displayed.

ID	Given Name	Surname	Full Name	Primary?	Position	AOU	Organisation	Organisation Name
100111743	Vaneet	Vaneet	Mr Vaneet Vaneet	Yes	Chief Investigator	MGN		

Given Name *

Vaneet

Surname *

Vaneet

Full Name *

Mr Vaneet Vaneet

System code of Position held *

Chief Investigator

User Person Code

100111743

Primary? *

☒ Yes

☐ No

AOU system code

MGN Sch Management

Organisation

Organisation Name

✓ ✗



Step 3: 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 / letter(s)
 - Scripts for recruitment telephone calls.
- Copies of the approval letters received from organisations involved in the research and/or organisations from which the data will be collected.
- 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.

The *Reference List* and *Research Tools* (or reasons as to why there aren't any) are mandatory attachments.

Navigation:

In the **Application Navigation** section, click the **Attachments** page.

Document Description	Reference (Document Title)	Additional Attachments		
		Soft Copy	Hard Copy	
* 1. Reference List	testdoc.txt	☒	☐	
* 2. Research Tools (or reasons as to why there aren't any)	testdoc.txt	☒	☐	
3. Participant Information Sheet (as applicable)			☐	
Consent Form (as applicable)			☐	
Others (as applicable)			☐	

Action: Click on the **Document Title**.

Result: The attachment will open in a new window.

Action: View the attachment and close the new window once you have finished.

Repeat this step until all attachments have been reviewed.

Note: There may be more than one page for the uploaded attachments; this is indicated by the page counter at the bottom of the attachments table.

Change page: < 1 2 > | Displaying page 1 of 2, items 1 to 10 of 13.

Change page: 1 Go Page size: 10 Change



ADDING AND DELETING COMMENTS

There are two types of comments. They are:

Page comments – comments specific to a page within an Application.

Application comments – overall comments about the Application.

Comments written by the Applicant or Supervisor are visible to all Investigators listed on the Application and the Ethics Reviewers.

Step 1: Adding Page Comments

Navigation:

Go to the **page** where you would like the **page comment** entered.

Test Student Application

Application Status: PS Review Workflow State: PS Review E2 Other Forms: Ethics Protocol

Form **Action**

Expand » Collapse «

Create New Ethics Application
✓ Create New Ethics Application

Investigator
✓ Investigator

Principal Supervisor

Ownership of Data

8.1 Detail who will own the data and the results of your research (student researchers normally own their own research and data unless there is a wr research and data is normally owned by UniSA). Please select all that apply. *

☒ UniSA
☐ Student researcher
☐ Other

8.2 Does the owner of the information or any other party have any right to impose limitations or conditions on the publication of the results of this pro

☐ Yes
☒ No

Action: In the Toolbar, select the **Page Comments** icon  and click the **New Comment** link.

Result: **Page Comments** screen is displayed.

Page Comments

New Comment Mark Selected Comments as Resolved

All

Type	Author	Date	Comments	Confidential?	Responded?	Resolved?
Type: ☐ General Note ☒ Action Note			Comments: Please change your answer in 8.1 to include Other			

Insert

No records to display.
Change page: < > | Displaying page 1 of 1, items 1 to 0 of 0.

OK

Update the **Page Comments** page as follows:

Type: Select **General** or **Action Note**.

Comments: Enter your **Comments**.

Note 1: Select **General Note** if you do not require action from the applicant.

Note 2: 4000 Character limit applies to **Comments** field.

Action: Select the **Save** icon  or the **Cancel** icon to cancel the comment 

Repeat these steps to enter page comments throughout the application.



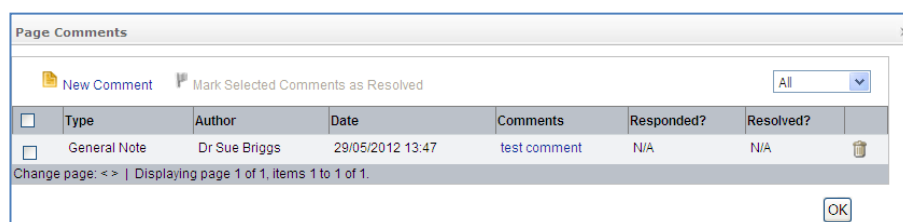
Step 2: Deleting Page Comments

Navigation:

Go to the **page** where you would like the **page comment** deleted.

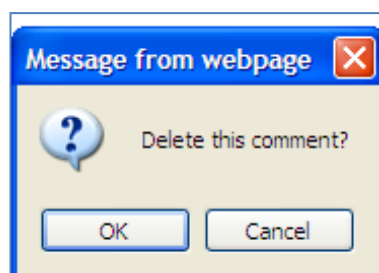
Action: In the Toolbar, select the **Page Comments** icon 

Result: **Page Comments** screen is displayed.



Action: Click the **Delete** icon next to the comment you wish to delete: 

Result: Warning message is displayed.



Action: Click **OK**.

Result: Page comment is deleted.

Step 3: Adding/Deleting Application Comments

Application-level comments can be entered from any page in the form. These comments are not linked specifically to any page – only to the application as a whole.

Navigation:

Go to the **any page** within the application

Action: Select the **Application Comments** icon  from the Toolbar.

Result: **Application Comments** screen is displayed.

Follow steps 1 and 2 above. Application Comments are added and deleted in the same way as page comments.



Step 4: 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 so, the Supervisor must mark the comments as 'resolved' before submitting the Application to the Ethics Compliance Officer.

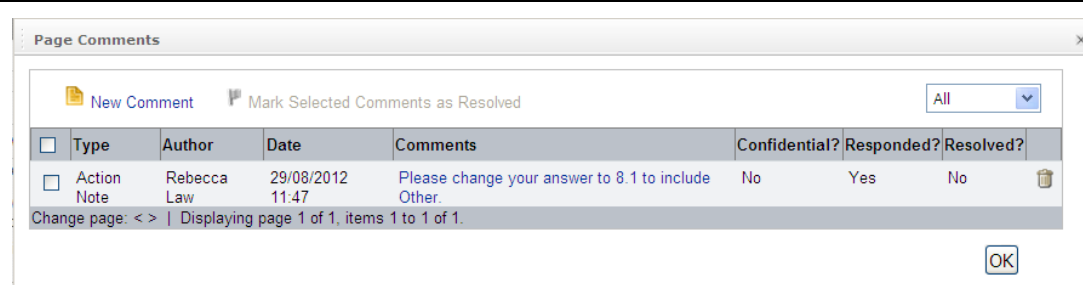
Otherwise, the Application must be reverted back to the student for further changes.

Navigation:

Identify the pages where the Application has responded to the **Action Note**.

Action: Select the relevant page and click the **Page Comments** icon  from the Toolbar.

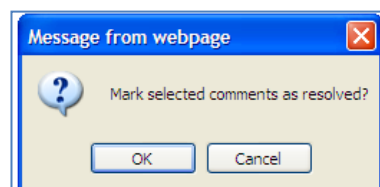
Result: **Page Comments** screen is displayed.



☐	Type	Author	Date	Comments	Confidential?	Responded?	Resolved?
☐	Action Note	Rebecca Law	29/08/2012 11:47	Please change your answer to 8.1 to include Other.	No	Yes	No

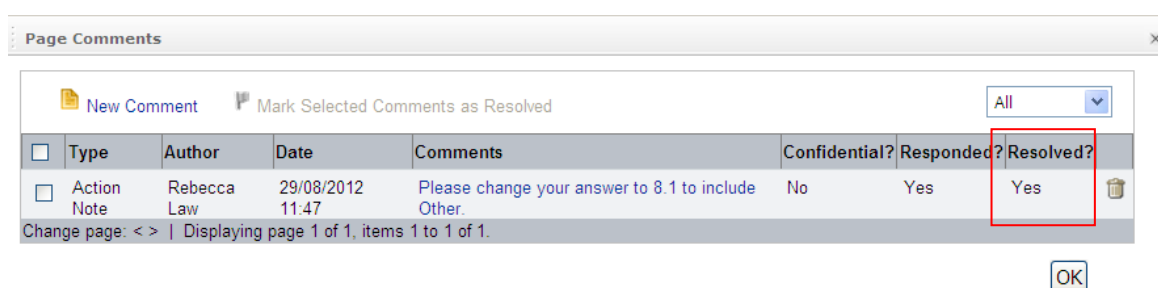
Action: Click the checkbox next to the relevant comment you wish to mark as resolved and click the **Mark Selected Comments as Resolved** link.

Result: Confirmation Message is displayed.



Action: Click **OK**.

Result: Action Notes are Marked as **Resolved**



☐	Type	Author	Date	Comments	Confidential?	Responded?	Resolved?
☐	Action Note	Rebecca Law	29/08/2012 11:47	Please change your answer to 8.1 to include Other.	No	Yes	Yes



VIEWING A PDF COPY OF THE APPLICATION

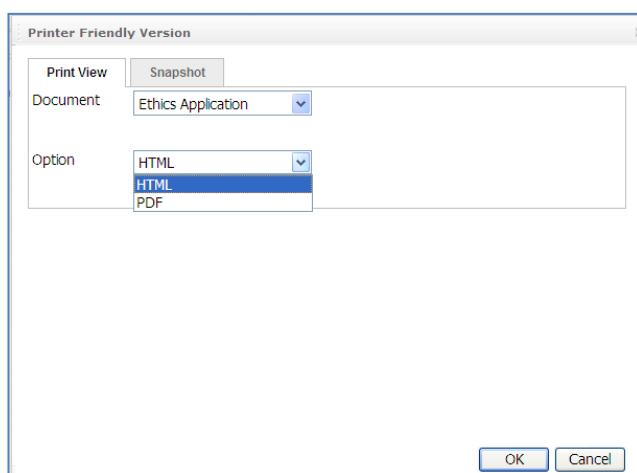
This function allows the Principal Supervisor to view the full Application as a single PDF or HTML file. This document can be printed and saved.

Note: Attachments are not included in the PDF and must be opened separately.

Step 1: Generating a PDF Copy of the Application

Navigation:

Within the toolbar, click the **Reports**  icon



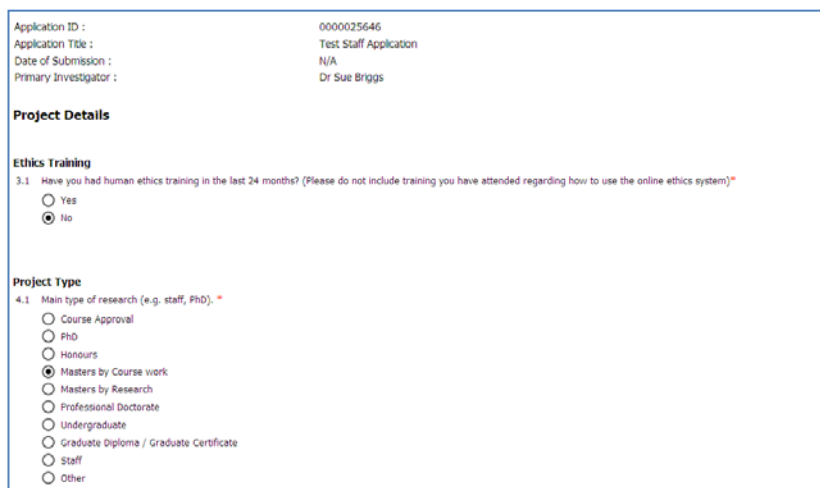
On the **Printer Friendly Versions** page:

Document: Select **Ethics Application** (Note: a summary of all Comments on the application can be viewed by selecting 'Comments Report').

Options: Select either **PDF** or **HTML**.

Action: Click **Ok**.

Result: The document opens in a new screen. Note: if the window does not open, check your Browser Settings to ensure that 'Pop Ups' are enabled.





SUBMITTING/REVERTING APPLICATION

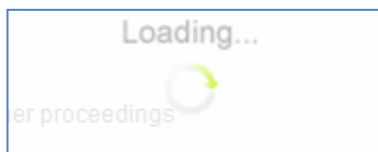
Once the Principal Supervisor has reviewed the full Application and Attachments, he/she can either revert the Application back to the student if changes are required, or submit the Application to the Ethics Compliance Officer. This is done via the 'Action' tab:

The screenshot shows a web interface for an application. At the top, it says 'Application Status: PS Review' and 'Workflow State:'. Below this are two tabs: 'Form' and 'Action'. The 'Action' tab is highlighted with a red rectangle. Under the 'Action' tab, there is a list of options: 'Withdraw', 'Submit', 'Revert', and 'Delete'.

Step 1: Reverting the Application

Action: Select the **Action** tab and click the **Revert** link.

Result: Loading page is displayed.



The **Status** of the application will now change to **PS Update Required**. The Application has been sent back to the student so that they can make the necessary amendments.

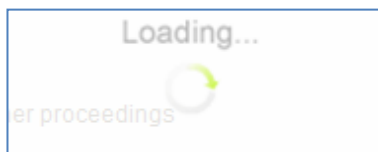
Test Student Application

Application Status: PS Update Required Workflow State: PSUpdate

Step 2: Submitting the Application

Action: Select the **Action** tab and click the **Submit** link.

Result: Loading page is displayed.



The **Status** of the application will now change to **Exempt/Negligible** or **ECO Review**.



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EMAIL NOTIFICATIONS

Emails will be sent to the Applicant, all Investigators and Principal Supervisor 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.

AMENDING AN APPROVED APPLICATION

Amendment requests are submitted and reviewed outside of the Online System. The application process is outlined here: <http://www.unisa.edu.au/res/ethics/human/amendments.asp>

TROUBLESHOOTING

If you are having trouble logging into the System or reviewing an Application, please contact the ethics enquiries team on: 830 23723 or via email: humanethics@unisa.edu.au

If you require ethics advice or guidance, please contact the relevant Research Ethics Advisor: see <http://w3.unisa.edu.au/res/ethics/human/reas.asp>.



APPENDIX

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. The Applicant is free 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.
Draft	An Applicant has started an Application. It has not yet been submitted.
E1 – HREC Chair	The Ethics and Compliance Officer has forwarded the Application for review. At the time the Application was submitted, the System 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 or HREC for E1 review. The Chair or Deputy Chair of HREC review E1 Applications within 10 working days of submission.
E2 – Committee Group Review	The Ethics and Compliance Officer has forwarded the Application for review. At the time the Application was submitted, the System determined that the research project poses only one potential foreseeable risk, that of 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 a Research Ethics Advisor. The review panel reviews E2 Applications within 10 working days of submission.
E3 - HREC	The Ethics and Compliance Officer has forwarded the Application for review. At the time the Application was submitted, the System 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 monthly meeting.
ECO Review	An Applicant has completed an Application and has submitted it to the Ethics and Compliance Officer, who conducts an initial check for completeness and consistency.
ECO Update Required	The Ethics and Compliance Officer 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 has determined that the research is exempt from further review as the project involves the use of archived data only and the data collected is de-identified (i.e. does not contain personally identifiable information) and will not reported beyond the University.
Negligible	The Applicant has submitted an Application and the System has determined that the research does not require further review as the project is either being • 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 but may be published externally however: - o the data was gathered online or in writing, - o the responses were provided voluntarily, - o the respondents were advised of the possibility that the data could be used for such purposes, and - o the anonymity of the respondents is maintained.
Not Approved	The Committee Review Group has reviewed the Application and is not satisfied that the project meets the requirements of the National Statement, nor that it can meet the requirements of the National Statement 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. However, it could meet the 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.
PS Review	An Applicant has completed an Application and submitted it for review by their Primary Supervisor (PS).
PS Review – ECO Update	Supervisor to review changes made by the Applicant, in response to the Ethics and Compliance Officer’s (ECO) comments.
PS Review – Review Update	Supervisor to review changes made by the Applicant, in response to the Review Group’s (during E1, E2 or E3 review) comments.
Withdrawn	The Ethics and Compliance Officer 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.



COMMON TERMS	
Term	Definition
Committee Review Group	Refers to one of three review groups that assess human ethics Applications. They are: E1 – HREC Chair or Deputy Chair E2 –Review Panel (HREC Chair/Deputy and a Research Ethics Advisor) E3 – Review by full Ethics Committee
ECO	Ethics and Compliance Officer
HREC	Human Research Ethics Committee
REA	Research Ethics Advisor

TOOLBAR		
Icon	Name	Description
	Next Page	Go to the next page in the application
	Previous Page	Go to the previous page in the application
	Save	Save the application
	Application Comments	Comments that apply to the application overall
	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
	Page Comments	Comments that apply to the current page
	Help	Help for the page or for the questions
	Exit	Exit the application and return to the Applications home page



COMMENT FLAGS	
Flag	Description
Red 	A reviewer has entered an action comment on the page
Yellow 	The applicant has responded to the action comment
Green 	The reviewer has resolved the action comment
Blue 	There is a general note on the page or application. This should be read, but no action is required.