



University of South Australia

User Guide

Human Research Ethics Application and Review System

Principal Supervisor Guide

Version 3

Research and Innovation Services

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

This is an official document of the University of South Australia for internal use only. The document has been prepared by Research and Innovation Services for web use and will be maintained on a regular basis. To ensure you have the most recent version it is advised that you access this document from its original location and do not keep local copies. The reader should be aware that this document is for the University of South Australia's employees' and students' information only and nothing contained in this information should be construed as an offer of service by the University of South Australia, form part of the terms of any agreement, or be legally binding on the University of South Australia.

Copyright University of South Australia all rights reserved.



Contents

OVERVIEW: HUMAN RESEARCH ETHICS APPLICATION AND REVIEW SYSTEM.....	3
GETTING STARTED	4
Step 1: Logging In	4
Step 2: Applications for Review	5
REVIEWING THE APPLICATION	7
Step 1: Navigating the Application.....	7
Step 2: Viewing Investigators	7
Step 3: Viewing Attachments	9
ADDING AND DELETING COMMENTS.....	10
Step 1: Adding Page Comments.....	10
Step 2: Deleting Page Comments	11
Step 3: Adding/Deleting Application Comments	11
Step 4: Reviewing Responses to Comments.....	12
VIEWING A PDF COPY OF THE APPLICATION.....	13
Step 1: Generating a PDF Copy of the Application	13
SUBMITTING/REVERTING APPLICATION.....	14
Step 1: Reverting the Application	14
Step 2: Submitting the Application	14
EMAIL NOTIFICATIONS	15
AMENDING AN APPROVED APPLICATION.....	15
TROUBLESHOOTING.....	15
APPENDIX.....	16
APPLICATION STATUS.....	16
COMMON TERMS	18
TOOLBAR.....	18
NAVIGATION ICONS	18
COMMENT FLAGS.....	19



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* (https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_may_2015_150514_a.pdf),
- b. the *Australian Code for the Responsible Conduct of Research* (http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/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 application and 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.

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.



GETTING STARTED

Step 1: Logging In

Navigation:

<https://rme.unisa.edu.au/RME6/>

ResearchMaster Enterprise
Please Log In To Continue

User Name *

Password *

Login

ResearchMaster Enterprise 6.12.1
Copyright © 2017 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:
Click on **Applications**

University of South Australia

Research Management System

Home Help Logout

Research Management System
Home Page

Resources

- [Click here to access guidance on the Online Human Ethics Application process.](#)

Online Forms
Ethics Applications
Applications

Login id: kasimoje [WEL001] ResearchMaster Enterprise 6.13.0 (38367) Copyright © 2017 ResearchMaster Pty Ltd

University of South Australia

Home Ethics

Applications

Create Application
My Applications
Draft
For Review
For Assessment Review
All Applications

Action: Click on **My Applications** or **All Applications**.
Result: Applications available for supervisor review are displayed.
Note: Applications are grouped according to their status.



Home **Ethics** Help

Applications

- Create Application
- My Applications
 - Approved
 - Approved Subject To
 - Closed Off
 - Draft
 - PS Review
 - For Review
 - For Assessment Review
 - All Applications

Type	Application ID	Application Title	Status	Primary Investigator	Process Stage	Template Name	Application Date
HUMAN	000029236	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](#)).

200007 : New test ethics E3 application

Application Status: **Approved** Workflow State: **E3Final** Other Forms: Ethics Protocol v2.4.3

Form **Action**

Expand » Collapse «

- Create New Ethics Application
- Investigator
- Prior Assessment
- Project Scope
- Project Details
- Resources
- Research type and participants
 - Research type

Create New Ethics Application

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 User 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 reviewer's 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 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 (function available on the left hand menu available from the Attachments Section), or as a page comment. Please refer to the User Guides if you are unsure how to use these functions.



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.
2. **Toolbar:** Located under the Information Area, the Toolbar provides actions available to view and review the application. Further 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.

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

Result: Additional information about the investigator is displayed.



Given Name *
Le
Surname *
Bui
Full Name *
Ms Le Bui
System code of Position held *
Chief Investigator <input type="button" value="v"/>
User Person Code
135123
Primary? *
<input checked="" type="radio"/> Yes <input type="radio"/> No
AOU system code
Organisation
Organisation Name
<input type="button" value="OK"/> <input type="button" value="Cancel"/>



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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
* 2. Research Tools (or reasons as to why there aren't any)	testdoc.txt	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3. Participant Information Sheet (as applicable)			<input type="checkbox"/>	
Consent Form (as applicable)			<input type="checkbox"/>	
Others (as applicable)			<input type="checkbox"/>	

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.

The screenshot shows the 'Test Student Application' interface. At the top, there are tabs for 'Form' and 'Action', with 'Expand »' and 'Collapse «' options. Below this is a sidebar with a tree view containing 'Create New Ethics Application', 'Investigator', and 'Principal Supervisor'. The main content area is titled 'Ownership of Data' and contains two questions: 8.1 'Detail who will own the data...' with checkboxes for 'UniSA', 'Student researcher', and 'Other'; and 8.2 'Does the owner of the information...' with radio buttons for 'Yes' and 'No'.

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

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

The screenshot shows the 'Page Comments' dialog box. It has a toolbar with 'New Comment' and 'Mark Selected Comments as Resolved' buttons. Below is a table with columns: 'Type', 'Author', 'Date', 'Comments', 'Confidential?', 'Responded?', and 'Resolved?'. The 'Type' section has radio buttons for 'General Note' and 'Action Note'. The 'Comments' field contains the text 'Please change your answer in 8.1 to include Other'. There is an 'Insert' button and a status bar at the bottom that says 'No records to display. Change page: <> | Displaying page 1 of 1, items 1 to 0 of 0.' and an 'OK' button.



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  to save the comment or the **Cancel** icon  to cancel the comment


Repeat these steps to enter page comments throughout the application.



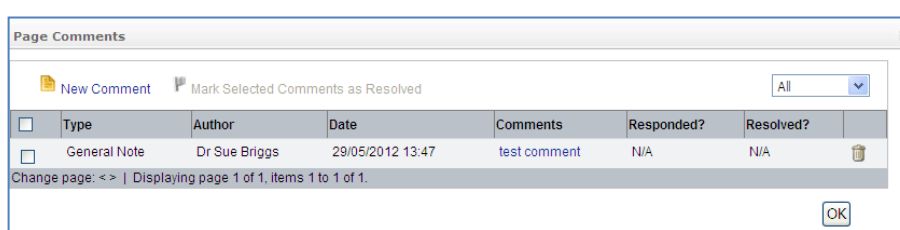
Step 2: Deleting Page Comments


Navigation:

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

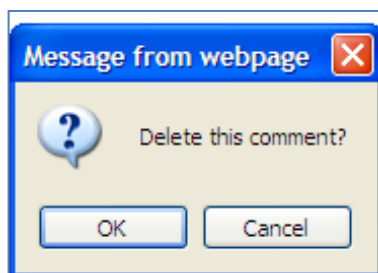
Action: In the Toolbar, select the **Page Comments** icon 

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.

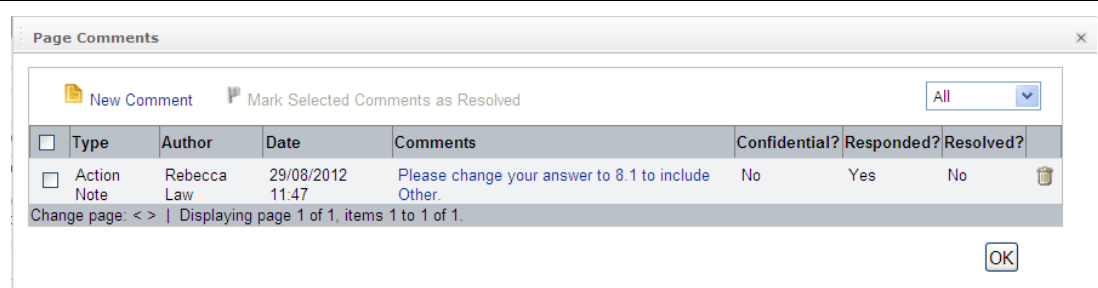
Otherwise, the Application must be reverted back to the student for further changes.

Navigation:

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

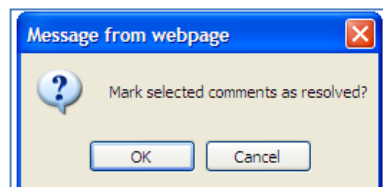
Action: Select the relevant page and click the **Page Comments** icon  from the Toolbar.

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



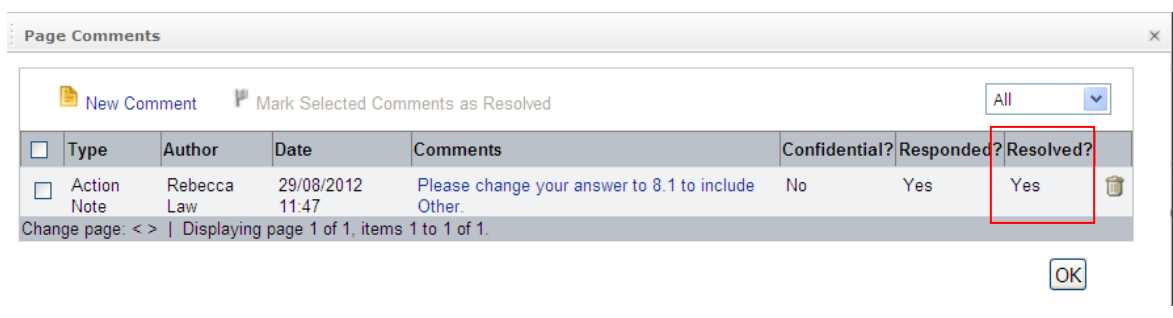
Action: Click the checkbox next to the relevant comment you wish to mark as resolved and click the **Mark Selected Comments as Resolved** link.

Result: Confirmation Message is displayed.



Action: Click **OK**.

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






VIEWING A PDF COPY OF THE APPLICATION

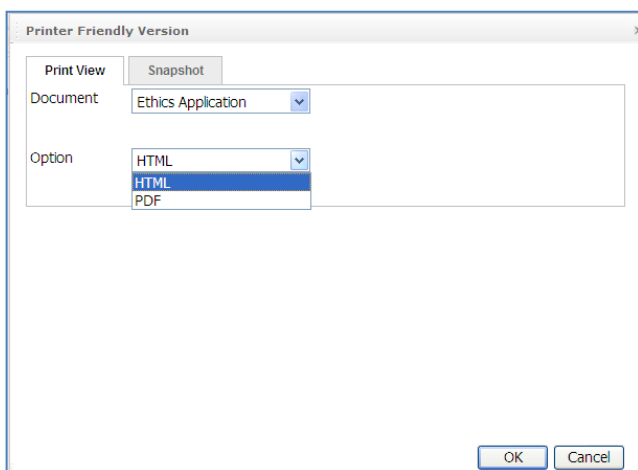
This function allows the Principal Supervisor to view the full Application as a single PDF or HTML file. This document can be printed and saved.

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



Printer Friendly Version

Print View Snapshot

Document: Ethics Application

Option: HTML (selected), HTML, PDF

OK Cancel

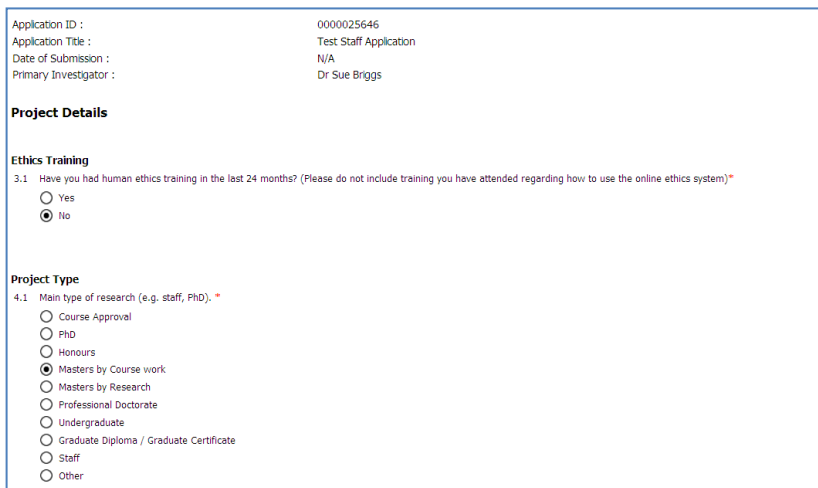
On the **Printer Friendly Versions** page:

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.



Application ID : 0000025646
Application Title : Test Staff Application
Date of Submission : N/A
Primary Investigator : Dr Sue Briggs

Project Details

Ethics Training

3.1 Have you had human ethics training in the last 24 months? (Please do not include training you have attended regarding how to use the online ethics system)*

Yes
 No

Project Type

4.1 Main type of research (e.g. staff, PhD).*

Course Approval
 PhD
 Honours
 Masters by Course work
 Masters by Research
 Professional Doctorate
 Undergraduate
 Graduate Diploma / Graduate Certificate
 Staff
 Other



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:

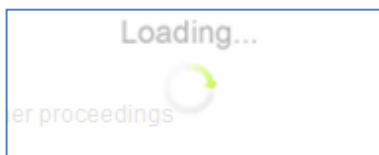
Application Status: PS Review Workflow State:

Form	Action
Withdraw	
Submit	
Revert	
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.

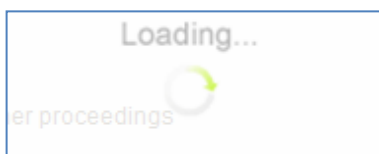
Test Student Application

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**.



University of South Australia

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	<p>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.</p> <p>The Chair or Deputy Chair of HREC review E1 Applications within 10 working days of submission.</p>
E2 – Committee Group Review	<p>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.</p> <p>The review panel reviews E2 Applications within 10 working days of submission.</p>
E3 - HREC	<p>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.</p> <p>HREC reviews E3 Applications at their next monthly meeting.</p>
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 <ul style="list-style-type: none">• 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:<ul style="list-style-type: none">○ 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.
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
	Action	Drop-down menu that lists the possible actions for the application, such as Withdraw, Submit, Delete
	Save	Save the application
	Form Comments	Comments that apply to the application overall
	Page Comments	Comments that apply to the current page
	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
	Help	Help for the page or for the questions
	Exit	Exit the application and return to the Applications home page
NAVIGATION ICONS		
	Next Page	Go to the next page in the application
	Previous Page	Go to the previous page in the application



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.