![University of South Australia logo]

University of South Australia

User Guide

Human Research Ethics Application and Review System

Applicant Role

Version 1

Research and Innovation Services

For further information or to update this document contact:
Compliance Officer, Research and Innovation Services

University of South Australia

Contents

OVERVIEW: HUMAN RESEARCH ETHICS APPLICATION AND REVIEW SYSTEM

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 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).

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/

Action: Enter your UniSA network **User Name** and **Password** and click the **Login** button.
Result: User is logged into the system with **Home** page displayed.

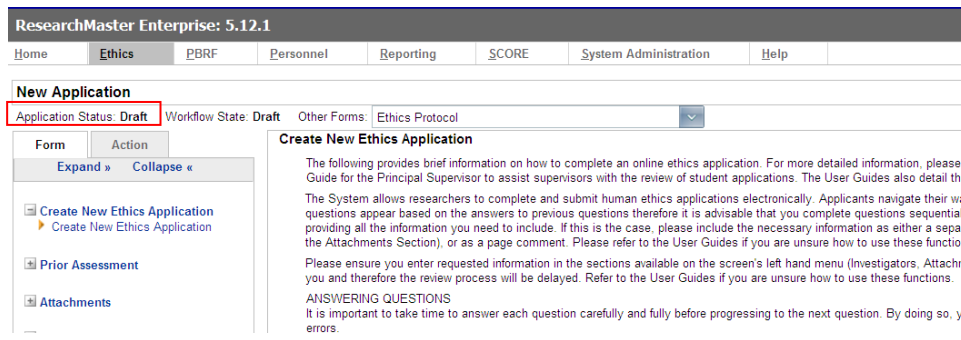# Step 2: Creating a New Application

Navigation:

Ethics Tab→Applications

Action: Click on **Create Application**.

Result: A new Application is created with an initial status of Draft.

Alternate Step 2: Accessing Existing Application(s)

Navigation:
Ethics Tab→Applications

Action: Click on **My Applications** or **All Applications**.
Result: Available applications are displayed.
Note: *Applications are grouped according to their status. Applications can be completed progressively and do not have to be completed in one sitting.*

THE ETHICS APPLICATION

Step 1: Navigating the Application

> **Navigation:**
>
> An application is created or opened (see Getting Started).

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 in the top-right corner of the application, the Toolbar provides actions available to view and review the application. Icon descriptions can be found in the Toolbar table at the appendix.

3. **Application Navigation:** Located on the left side of the application, the Navigation section provides access to sections within the application (**Form** tab), and available actions (**Actions** tab). The **Form** tab shows the Sections and Pages within the Sections, providing Expand and Collapse links to view the whole structure. The **Action** tab contains the action(s) (ie, Submit) available for the current workflow state.

4. **Application Content:** The main section of the screen, displays the application questions and responses. Note AOU is the Applicant's Originating Unit which refers to the applicant's own school.

Step 2: Answering Questions in the Application

Questions within the Application require answers in different formats – Yes/No, numerical and text responses. The Applicant can answer questions in any order. However, some questions are dependent on the answer provided to an earlier question. If you change the answer to one question, this may cause new questions to appear and previously answered questions to disappear. This may result in pages that have been marked 'completed' no longer being marked 'completed'.

Note: Answers are saved automatically. If you exit a page or navigate to another page, the answers entered up to that point will be saved automatically.

Step 3: Adding Investigators

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

Action: Enter the investigator's UniSA staff/student ID or first name or last name or full name in the text box.
Then, click the 🔍 icon.
Result: A list of staff members meeting the criteria is displayed.

Search & Add Person

Found 22 Matching Personnel
Please select and add a person form the list below by clicking on the preferred name

Preferred Name	ID	Gender	Type	Classification	School	Division
Ms Alison Ballantyne	09401965C	Female	Student	Academic	Sch Nursing & Midwifery	Division of Health Sciences
Dr Andrew Allan	053205	Male	Internal	Academic	Sch Natural & Built Environme...	Div of Info Technology, Engin...
Dr Kerry Mallan	MALLANK	Female	External			
Mr Victor J Callan	CALLANV	Male	External			
Stephen McFallan	MCFALLAN	Male	External			
A/Prof Judith Rivalland	RIVALLANDJ	Male	External			

Action: Select the investigator from the list.

Result: The details of the selected person will be displayed.

Action: Input appropriate details and click the 🗸 icon to Save.

Result: Investigator added.

Step 4: Selecting the Chief Investigator

As a default the Applicant is assigned the role of Chief Investigator. This step is only required if the Applicant is not the Chief Investigator.

Navigation:

Select the *Investigator* page under the *Investigator* section.

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

Result: Additional information about the investigator is displayed.

Action: Select **System code of Position held** as *Chief Investigator,* **Select Primary** as *Yes* and click the ✔ icon to Save.

Result: Chief Investigator is set.

Step 5: Removing an Investigator

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

Action: Click the 🗑 icon against the name of the Investigator to be deleted
Result: A warning message is displayed

Action: Select OK
Result: Investigator is deleted.

Step 6: Adding Principal Supervisor

If the Applicant is a student then a Principal Supervisor must be identified. A Principal Supervisor is not required for a staff member applicant.

The Principal Supervisor cannot be added with an Investigator role, but any other supervisors must be entered with 'Other Investigator' roles (Step 3: Adding Investigators).

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

Action: Select Yes to question 1. Is the primary applicant a student?

Result: Principal Supervisor section will be accessible.

Action: Select *Principal Supervisor* page under the *Principal Supervisor* section.

Result: Principal Supervisor page will be displayed.

Action: Enter the principal supervisor's UniSA staff/student ID or first name or last name or full name in the text box. Then, click the 🔍 icon.

Result: A list of UniSA personnel meeting the criteria is displayed.

Note: The Principal Supervisors can also have a student ID attached to them. Make sure you select the Staff record of the Principal Supervisor.

Search & Add Person

Found 2 Matching Personnel
Please select and add a person form the list below by clicking on the preferred name

Preferred Name	ID	Gender	Type	Classification	School	Division
Mr Vaneet Vaneet	100111743	Male	Student		Sch Management	Division of Business
Mr Vaneet Vaneet	128757	Male	Internal	General	Research and Innovation Servi…	Research & International Port…

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

Action: Select the Principal Supervisor from the list.

Result: The details of the selected person will be displayed.

Action: Input appropriate details and click the icon to Save.

Result: Principal Supervisor added.

Step 7: Removing the Principal Supervisor

Navigation:

Select the *Principal Supervisor* page under the Principal Supervisor section.

ID	Given Name	Surname	Full Name	Primary?	Position	AOU	Organisation	Organisation Name	Supervisor	
128757	Vaneet	Vaneet	Mr Vaneet Vaneet	No	Supervisor	ORC				🗑

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

Result: A warning message is displayed
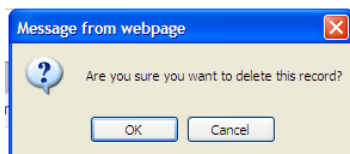
Action: Select **OK**

Result: Principal Supervisor is deleted.

University of South Australia

Step 8: Submitting a completed Form / application

The Ethics application can only be submitted when all mandatory questions in the form have been answered. This is true if the ✔ appears next to each item on the Application navigation (Hint: use Expand link to check all items)

Navigation:
Select Action tab.

Action: Click the **Submit** button.
Result: Warning message is displayed.
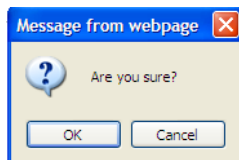
Action: Click **OK.**
Result: If the form is complete, the Applicant is informed of the level of the risk associated with the project.
If the form is incomplete, an error message will appear informing the Applicant that their form cannot be submitted. This will display above the Application title. Return to the Form tab to determine what needs to be completed.

The Application has been submitted and the Application Status and Workflow State changes to one of the following:
   a. If the Application is considered *Exempt* or *Negligible*, the Applicant is informed that no additional review is required and they can commence their research.
   b. If the Application does not meet the conditions for *Exempt* or *Negligible*, then that Application changes from *Draft* to *ECO Review (for a staff application), or Draft to PS Review (for a student application)*. The Applicant will also be informed of the risk associated with their research (E1, E2 or E3).

Step 9: Adding Attachments

The purpose of the Attachments page of the Application is to enable the Applicant to attach documents to support their Application. This includes, but is not limited to:

- A copy of the HREC Application submitted and approved by another institution's HREC (i.e. other than UniSA HREC).
- Copies of the approval letters received from organisations involved in the research and/or where the data will be collected from.
- The research tools:
  - Questionnaire(s).
  - Interview schedule(s).
  - Focus group / interview topic(s).
- The recruitment material:
  - Recruitment flyer / letter(s).
  - Participant Information sheet(s).
  - Participant Consent form(s).
- A copy of the confirmation of insurance cover from UniSA's Insurance Officer.

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

Note: If documents cannot be attached electronically, a hard copy of the document(s) must be forwarded to the Principal Supervisor, and once the Principal Supervisor has approved the application, these documents must be forwarded to the Ethics and Compliance Officer. Neither the Principal Supervisor nor the Ethics and Compliance Officer can submit the Application for review by the next review stage in the workflow until all supporting documents are received.

It is advised that, wherever possible, documents are scanned and attached using the Attachments page.

*Also, the system can only accept a **maximum of ten** attachments. If there are more than ten documents to upload, please combine the additional documents into one zip file.*

Navigation:

Select the *Attachments* page under the *Attachment* section.

Action: Click the icon next to the document type you would like to upload.

Result: *Upload File* form will appear.

Action: Search for the file, provide a description (optional), and click the OK button to upload the file.

Result: the name of the uploaded file will appear under the Reference (Document Title) column of the Attachments table.

Additional Attachments

Document Description	Reference (Document Title)	Soft Copy	Hard Copy	
Participant Information Sheet	onlinethics.txt	☑	☐	🗑

Action: Add an additional document description. Click *Additional Attachments* link, at the top-right part of the Attachments table and enter a Document Description name in the text box displayed. Click the ✔ to save the new document type.

Result: A new document type is added and an attachment can be added.

3. Participant Information Sheet (as applicable)		📤	☐	🗑
Consent Form (as applicable)		📤	☐	🗑
Others (as applicable)		📤	☐	🗑
Sample Document Description	*		☐	☐	✔ ✖

Step 10: Viewing Attachments

Navigation:

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

	Document Description	Reference (Document Title)	Soft Copy	Hard Copy	
*	1. Reference List	testdoc.txt	☑	☐	🗑
*	2. Research Tools (or reasons as to why there aren't any)		📗⬆	☐	🗑

Additional Attachments

Action: For soft copies 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

Step 11: Deleting Attachments

Navigation:

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

	Document Description	Reference (Document Title)	Soft Copy	Hard Copy	
*	1. Reference List	testdoc.txt	☑	☐	🗑
*	2. Research Tools (or reasons as to why there aren't any)		📗⬆	☐	🗑

Additional Attachments

Action: Click the 🗑 icon against the name of the attachment to be deleted

Result: A warning message is displayed

Message from webpage

❓ Are you sure you want to delete this record?

OK   Cancel
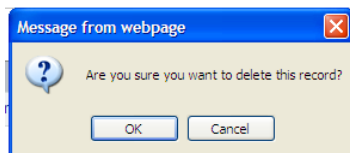
Action: Select **OK**

Result: Attachment is deleted.

Step 12: Adding Page 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 another Investigator are visible to all Investigators listed on the Application and whoever reviews the Application. Thus they are visible to the Principal Supervisor, Ethics and Compliance Officer and the members of the Committee Review Group.

Navigation:

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

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

Result: Page Comments screen is displayed.

Action: Select the **New Comment**.

Result: Comments box is provided.
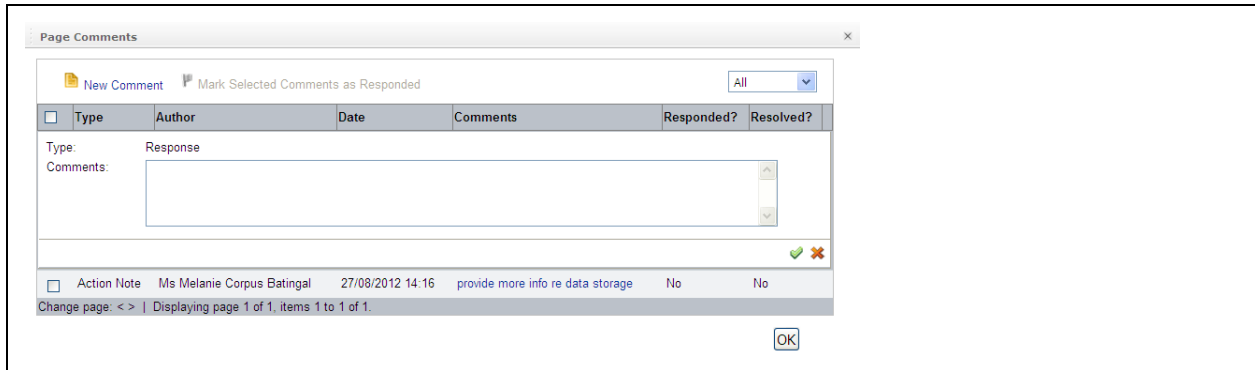
Action: Select the **Save** icon to save the comment, or **Cancel** icon to cancel the comment.

Result: Record is saved/cancelled.

Action: Repeat these steps to enter page comments through the application.

Result: Comments are added successfully.

Step 13: Deleting Page Comments

Navigation:

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

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

Result: Page Comments screen is displayed.
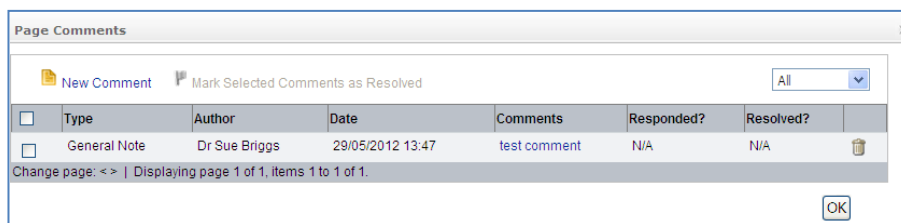
Action: Click the **Delete** icon next to the comment you wish to delete.

Result: Warning message is displayed.
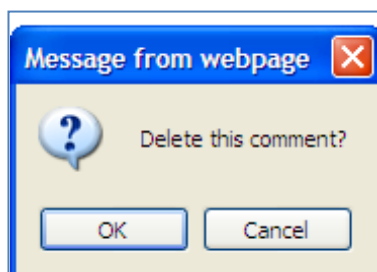
Action: Click **OK.**

Result: Page comment is deleted.

Step 14: 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.
Repeat steps 8 and 9 within this section to add and delete **Application Comments.**

Step 15: Submitting a completed Form / application

Repeat Step 8: Submitting a completed Form / application.
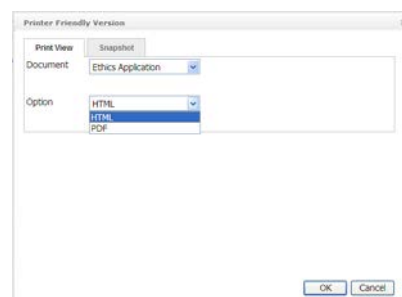
Step 16: Printing the Application

This function allows the Applicant to view the Application as a PDF or HTML file, enabling the Applicant to view their answers without navigating the System.

Navigation:

Click the **Reports** icon from the toolbar.

Action: Select the Ethics Application from the Document field and select the either HTML or PDF. Select OK.

Result: Document will display in a new screen.

Action: Document can be printed or saved.

Note: A PDF copy for both Ethics E1 and Ethics E2 forms of the Application is necessary to get the complete details.

Step 17: Responding to Reviewer's Comments

Once the Application has been submitted for review, the Application may be returned to the Applicant with Page Comments and/or Application Comments entered by the reviewer. This means that the Applicant is required to make changes to the Application. The Application will therefore be returned to the Applicant with one of the following status:

- ECO Update Required
- PS Update Required (for student applications)
- Approved Subject To
- Not Approved: Resubmit.

The process of responding to these comments is the same regardless of who wrote the comment.

A reviewer can enter two types of comments:

- General Comments
- Action Comments

Action Comments require the Applicant to respond to the comment and mark the item as 'responded' before they can resubmit the Application. General Comments do not require a response but should be viewed.

Navigation:

Select the relevant Application from the My Applications list. For this example, the application has the status *ECO Update Required.*

Action: Check the sections/pages which have the action comment icon ⚑ next to them (Hint: Use the *Expand* link). Go to this section/page.

Result: Action comment icon displayed.

Action: Click the **Page Comments** 🗎 icon. You should see the Action Notes created by the ECO or Committee Review Group. Click the link on the Comments column to view the whole comment.

Result: Action note is displayed.

Action: Once the comment is read and the action understood select OK

Result: Action comment will close.

Complete the required action

Action: Reopen action comment and check box next to action note.

Result: The 🚩 Mark Selected Comments as Responded will be enabled.
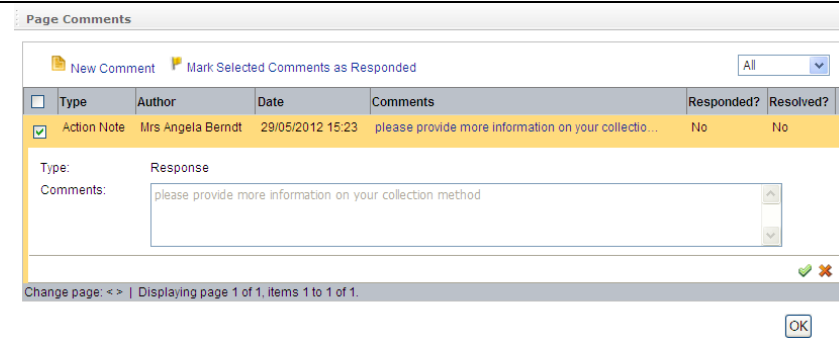
Action: Select 🚩 Mark Selected Comments as Responded

Result: Warning message.
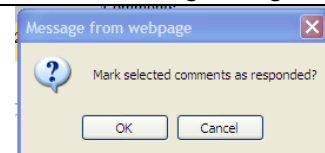
Action: Select OK.

Result: The value of the **Responded** column for this Action Note will change from No to Yes. The marker for the page will also change from 🚩 to 🚩, indicating that the action note for that page has been responded to.

Note: An Application can only be resubmitted once all Action items (Page Comments and Application Comments) have been responded to and therefore contain the 🚩 *symbol. An Application cannot be resubmitted if there is a* 🚩 *symbol on the Application navigation (Form tab) area.*

Submitting the Application
Once all action items and general comments have been responded to, the Application can be resubmitted.
Refer to the Submitting a Completed Form/Application for the steps.

EMAIL NOTIFICATIONS

Emails will be sent to all 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.

AMENDING AN APPROVED APPLICATION

Amendments to an Approved Application cannot be made within the System. The process for amendment of an approved application is detailed at: http://www.unisa.edu.au/res/ethics/human/amendments.asp

TROUBLESHOOTING

If you are having trouble logging into the System or completing the form, please contact ethics@unisa.edu.au
If you require assistance completing the Application, please contact your Research Ethics Advisor.

University of South Australia

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 Application is "Approved".
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.
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. |
| 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 the Applicant's Research Ethics Advisor.

The review panel reviews E2 Applications. |
| 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.

The HREC reviews E3 Applications at the next monthly meeting. |
ECO Review	An Applicant has completed an Application and submitted the Application for review. The Application is forwarded to the Ethics and Compliance Officer for review.
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 (ie 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 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 the Application for PS Review.
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.

COMMON TERMS	
Term	**Definition**
Committee Review Group	Refers to one of three review groups that assess human ethics Applications. They are: E1 – HREC Chair E2 – Committee Group Review E3 – HREC

University of South Australia

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