



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](mailto:humanethics@unisa.edu.au), ph. 830 23723

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## 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](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](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.

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## 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**

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# 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

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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

Action Save Form Comments Page Comments Reports Help Exit

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.



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





### 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 sections: 8.1 'Detail who will own the data and the results of your research...' with checkboxes for 'UniSA', 'Student researcher', and 'Other'; and 8.2 'Does the owner of the information or any other party have any right to impose limitations...' 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 the toolbar 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.



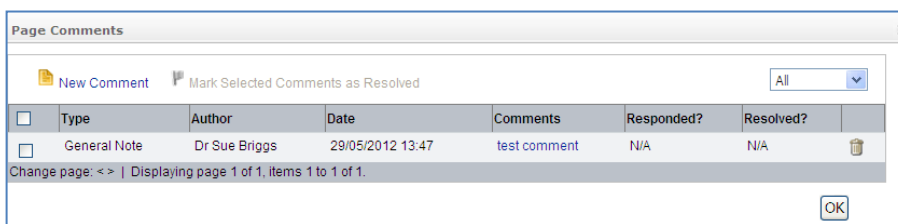
## Step 2: Deleting Page Comments


### Navigation:

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

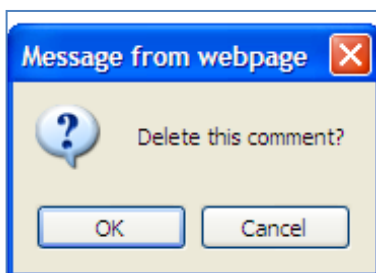
**Action:** In the Toolbar, select the **Page Comments** icon 

**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.

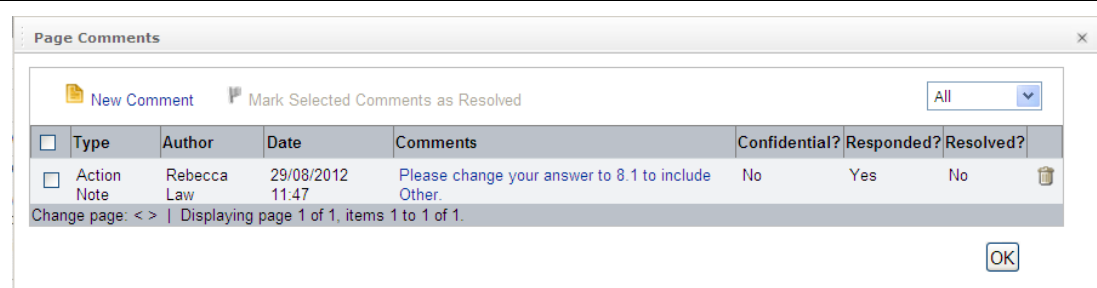
Otherwise, the Application must be reverted back to the student for further changes.

**Navigation:**

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

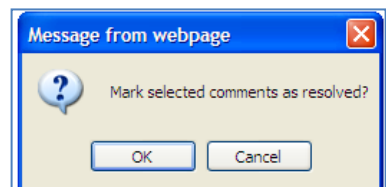
**Action:** Select the relevant page and click the **Page Comments** icon  from the Toolbar.

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



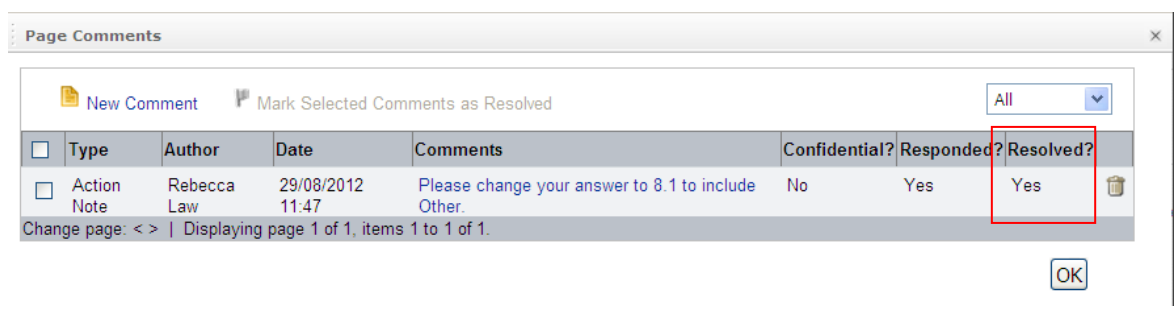
**Action:** Click the checkbox next to the relevant comment you wish to mark as resolved and click the **Mark Selected Comments as Resolved** link.

**Result:** Confirmation Message is displayed.



**Action:** Click **OK**.

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






## VIEWING A PDF COPY OF THE APPLICATION

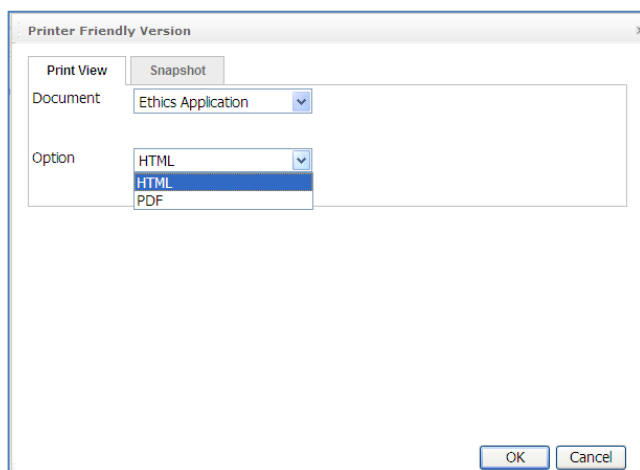
This function allows the Principal Supervisor to view the full Application as a single PDF or HTML file. This document can be printed and saved.

**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

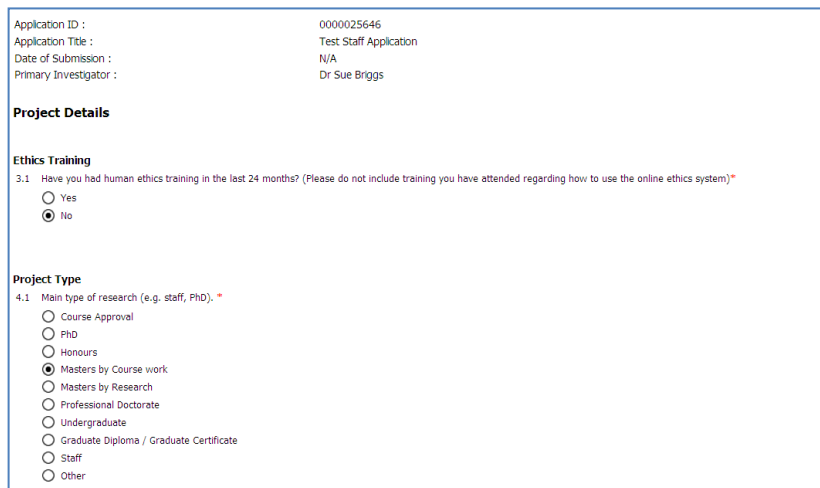
On the **Printer Friendly Versions** page:

**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:

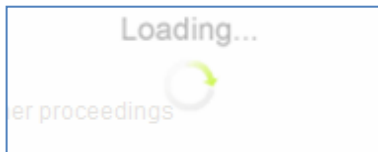
Application Status: PS Review    Workflow State:

|          |               |
|----------|---------------|
| Form     | <b>Action</b> |
| 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.

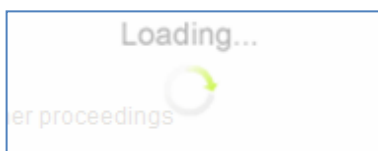
#### Test Student Application

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**.



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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](mailto: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

| <b>APPLICATION STATUS</b>   |   |
|-----------------------------|---|
| <b>Term</b>                 | <b>Definition</b>   |
| 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                | <p>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</p> <ul style="list-style-type: none"><li>• conducted solely for the purpose of internal quality assurance and will not be published or presented externally, or</li><li>• conducted solely for the purpose of internal quality assurance but may be published externally however:<ul style="list-style-type: none"><li>○ the data was gathered online or in writing,</li><li>○ the responses were provided voluntarily,</li><li>○ the respondents were advised of the possibility that the data could be used for such purposes, and</li><li>○ the anonymity of the respondents is maintained.</li></ul></li></ul> |
| 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.   |



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

| <b>TOOLBAR</b>          |               |   |
|-------------------------|---------------|---|
| <b>Icon</b>             | <b>Name</b>   | <b>Description</b>  |
|                         | 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   |
| <b>NAVIGATION ICONS</b> |               |   |
|                         | Next Page     | Go to the next page in the application  |
|                         | Previous Page | Go to the previous page in the application  |



| <b>COMMENT FLAGS</b>   |   |
|--|---|
| <b>Flag</b>  | <b>Description</b>  |
| 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. |