

UNIVERSITY
OF SOUTHERN
QUEENSLAND



Research Information Management System (RIMS)

Human Research Ethics (HRE) Module

HRE Application (for USQ Staff)
User Guide

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Human Research Ethics (HRE)


Applicant (Student) User Guide

1. What is RIMS?

Applications for human research ethics approval are processed through USQ's online application and approval system titled Research Information Management System (RIMS).

The RIMS system includes a very flexible eForm especially designed for completion by the HRE applicant. The system also includes a workflow system to allow the Research Integrity and Ethics office to electronically manage the endorsement / approval, review and reporting processes for all HRE applications.

RIMS provides assessors and committee members online access to request amendments, make comments, check related documents, and provide electronic sign offs. The RIMS system has visibility conditions so applicants only see relevant questions and information.

There is also online assistance and reference data for specific questions marked with the  symbol.

A summary of the RIMS features include the ability to:

- access the online forms from anywhere at anytime
- add comments at any stage of the review process
- record outcomes and conditions of approval
- print reports on application content, comments and document summaries
- track applications at all stages of the review process
- allow applicants to submit amendments and renewals for existing applications
- structure questions to allow risk assessment of protocols prior to submission
- create conditional workflow branching based on whether the applicant's answers determine the application to be low or high risk

The Office of Research will be able to:

- set up committee meetings and expedited review processes
- allocate applications to Committee meetings, panels and individual reviewers online
- facilitate pre-meeting committee reviews online

2. Accessing RIMS

2.1 Accessing RIMS

Open your desired Internet browser and select one of the options listed below to access the RIMS login page:

From the USQ Home Page (www.usq.edu.au)

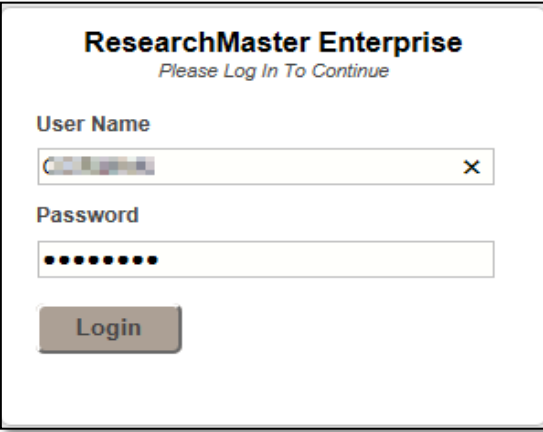
Click on **Research**

Click on **RIMS Login** link (*under Research support and development*)

2.2 Logging in to RIMS

At the ResearchMaster Log In pop up window:

- Enter your UConnect User Name and Password.
- Click on the Login button.



ResearchMaster Enterprise
Please Log In To Continue

User Name

Password

Login

Note: If you do not know or cannot remember your UConnect user name and/or password, contact the ICT Helpdesk on (07) 4631 1900 or by email ICT.ServiceDesk@usq.edu.au.

3. New HRE Application

3.1 Planning for your HRE Application

Applicants are requested to read Section 1 Values and principles of ethical conduct and Section 2 Themes in research ethics: risk and benefit, consent of the [National Statement on Ethical Conduct in Human Research, 2007](#), prior to commencing their human research ethics application. Additional sections specific to the research method or field, and/or the proposed participants may also need to be consulted, depending on the proposed project.

3.2 Creating a new HRE Application

- From the RIMS Home Page, Click on **Online Forms | Applications**
- Click on **Create Application | HRE Application**

3.3 Navigating within the HRE Application


3.3.1 Left-hand menu tabs

You will note that there is a menu located on the left-hand side of the page. The **Form tab** will display the e-form sections and pages that are contained within your application. These, will expand and contract, depending on the responses you provide to the questions contained in the main e-form window.

The **Review tab** will be used to nominate your Principal Supervisor and Head of Unit once you have completed your application.

The **Action tab** will be used to progress your application through the appropriate workflows.


3.3.2 Main e-form window

The main e-form window contains the questions you will complete within your HRE Application. Use the  help button at the end of questions to assist you in determining what the question is requiring you to think about prior to providing a response in this section.

3.3.3 Moving through the application


Navigate within your application by using the  and  buttons at the bottom of each e-form page. Alternatively, you can click on the page link within the left-hand menu.

Mandatory questions are denoted by *. You will not be able to submit your question if you have missed one of these.

Once all mandatory questions have been addressed, a  will appear against the page link to confirm that you have successfully completed this e-form page.

Ensure you use the **Exit** button  within the RIMS e-form to save and exit your work. **DO NOT** use the browser back button, or the browser's close or exit button.

3.4 Tips for completing the HRE Application

- Carefully read each question and ensure that you understand what it is asking you to respond to. Use the  help button at the end of a question to assist you as required.
- Provide your response to each question.

Notes:

- ¹ When entering text into a text box, you will be limited to 2,000 characters (including spaces). You will need to write succinctly.
- ² If you are unsure of what to include, you can Save and Exit your work and come back to your application at any time. Remember to note the interim application ID number.
- ³ The “Review outcome comments” text box at the bottom of each page will remain greyed out until after the ethical review of your application has been completed.

- **Question 1.1** prompts you to confirm if this research protocol has already been reviewed. Unless you are working on a multi-institutional collaborative project, indicate **NO** here.
- **Question 1.2** prompts you to confirm the type of research that your project will involve. Check all that apply.


Note:

- ¹ Genetic testing, analysis of genetic material and clinical trials are not to be submitted on this e-form. Contact the Ethics Team (email: human.ethics@usq.edu.au) before proceeding with your HRE Application.

➤ 6.2 Principal Investigator

- Ensure that you click on the linked name of the Principal Investigator and complete all required fields in the section.
- When complete, click on the **OK** button.

➤ 6.3 Other Investigators

- Click in the **Name/ID:** text box, enter the investigator name (or part of their name), and click on the  button.
- Select the investigator to be added from the returned list.
- Click on the **linked name** of the Other Investigator, complete all required fields in the section, and click on the **OK** button.

Notes:

- ¹ Add all staff and students that are associated with your project, including your supervisors and other students that may be working on this project with you.
- ² Use the “Co-Investigator” role for any Principal and Associate Supervisors associated with the project, due to current access restrictions associated with the supervision roles in the RIMS system.

➤ External Investigators

- Click on the **Add External Person** button, complete all required fields in the section, and click on the **OK** button.

➤ 11 – Data

- Refer to the USQ Library’s resources on [Research Data](#). Refer to your responsibilities as a USQ researcher within the [Australian Code for the Responsible Conduct of Research](#), and access USQ’s data management plan template from the “Managing Research Data” section.


➤ 16. Documents

- This is where you will upload your supporting documentation to the HRE Application.
- The Document RIC displays a list of potential documents as a prompt of what you may be required to provide. However you will need to make a decision based on your specific research project.
- You can only upload one document per prompt. Therefore, if you have multiple documents of a similar nature (for example, two different Participant Information Sheets), you can choose to upload one here, and add a new document for the second one.
- To add a new document, click on the **Add New Document** link.
- Follow the prompts to upload the electronic copy. Remember to carefully name your file with something meaningful for the reviewers, as the file name is what is referenced within the Document RIC.

➤ 17. Peer Review


- Follow the instructions to have your HRE Application peer reviewed prior to submission from the peer review link within the application.
- To print a hard copy of the application, refer to [Ethics Application Report](#).
- Upload a copy of your peer review statement to the application.

➤ Declaration

- Click on the  signature button.
- Complete the details within the section.
- Click on the **OK** button.

3.5 Obtaining Head of Unit endorsement

Once your application has been completed, documents uploaded, and peer reviewed, you will need to submit your application to your Head of Unit for endorsement. This may be your Head of School, Centre Director, etc.

- Log in to RIMS, and select your application.
- Click on the **Review tab**.
- Click on **Nominate head of unit**.
- Click in the Select Reviewer text box, enter the name of your head of unit, and click on  button.
- Select your head of unit's name from the returned list.
- Click on the **Action tab**.
- Click on the **Submit to Head of Unit for endorsement**.
- Click on the **OK** button, when prompted "This will submit the application to your nominated Head of Unit for endorsement...".

Notes:

1. The message bar will state "Your application has been submitted to your nominated Head of Unit."
2. The workflow state will change to "Awaiting Head of Unit endorsement".
3. Your Head of Unit will receive an email to notify them that there is an application in RIMS that requires their review and endorsement.
4. Your Head of Unit can either endorse your application (as submitted), or provide you with feedback for your consideration. If feedback is provided, you will notice blue flags will appear against the page/s where comments are provided. Refer to [Page Comments](#) to view and address these.

3.5.1 Addressing Head of Unit feedback (if applicable)

- Login to RIMS, and select your application.
- Navigate to the page that contains the comment.
- Read the comment, undertake any changes within the e-form (if required).
- Add a new comment to reply to your head of unit's feedback indicating if you have addressed this, or provide a response in defence (as required). Follow the instructions in the [Page Comments](#) section, and ensure you include the e-form section number at the commencement of each response so that your head of unit can match your response to the feedback they provided.
- If your head of unit has 'endorsed' your application, you can move to the next step of submitting your application for ethical review.
- If your head of unit has 'not endorsed' your application and wishes to review your responses to the feedback they provided, you will need to re-submit the application to them for endorsement.
 - Click on the **Action tab**.
 - Click on the **Resubmit to Head of Unit for endorsement**.
 - Click on the **OK** button, when prompted "This will submit the application to your nominated head of unit for endorsement....".

3.6 Submitting your HRE Application for ethical review

Once your application has been endorsed by your head of unit, it is ready to be submitted for ethical review.

- Login to RIMS, and select your application.
- Click on the **Action tab**
- Click on **Submit for ethical review** link
- Click on the **OK** button, when prompted "This will submit the application for an ethical review...".

Notes:

1. The message bar will state "Your application has been submitted for ethical review. One of our staff will be in contact with you shortly to discuss the next steps".
2. The application status will change to: "Submitted", and the workflow state will change to "Application submitted for ethical review".

3.7 Responding to ethical review feedback

Once your application has been ethically reviewed, it is likely that you will be provided some feedback to consider and/or address/defend to the satisfaction of the reviewers.

- Login to RIMS, and select your application.
- Navigate to the page that contains Review Outcome comments (at the bottom of each e-form page).
- Read the comment, undertake any changes within the e-form (if/as required).
- Respond to the Review Outcome comment, within the Applicant Response text box. Remember to include the corresponding e-form section number at the commencement of each response so that the reviewers can match this up.
- Click on the **Save** button.

3.8 Re-submitting your HRE Application

Once you have addressed and/or defended all Review Outcome comments, uploaded any revised/new documents, resubmit your application to the Ethics Office.

- Click on the **Action tab**.
- Click on the **Resubmit for ethical review**.
- Click on the **OK** button, when prompted “This will submit the application to your nominated head of unit for endorsement....”.

Note:

1. A **!** will appear against a page if a Review Outcome comment has not been addressed.
2. The message bar will state “Email notification sent to the ethics officers”.
3. The application status will change to: e.g., “Conditionally Approved”, and the workflow state will change to “Application resubmitted for ethical review”.

3.9 Obtaining final approval

Once your response to the reviewer feedback has been reviewed and deemed to be satisfactory, you will receive a USQ HREC approval certificate. Please check the general and specific conditions of your approval carefully, as it is your responsibility to comply with these for the duration of your ethical approval.

3.10 Commencing your research

All research at USQ is to be undertaken in accordance with the [Australian Code for the Responsible Conduct of Research](#) and the University’s [Research Code of Conduct Policy](#). Please familiarise yourself with these documents and any pursuant policies and procedures.

3.11 When things change


As Robert Burns once said, “The best laid schemes o’ mice an’ men”! This applies to ethics approvals too. No matter how carefully you have planned for your project and carefully documented this Investigators often come and go from project, and things may go awry.

If your human research **changes for any reason**, you must seek approval from the University and the USQ HREC via an amendment application prior to allowing any new investigators to undertake previously approved work and/or undertaking any work in a new way.

Normally, a HRE Amendment Application is a simple exercise to highlight where your original approved protocol has changed. This can be completed online. Refer to the HRE Amendment Application User Manual, or contact the Ethics Team for further information on (07) 4687 5703 or (07) 4631 2690 or by email human.ethics@usq.edu.au.

4. Page Comments

In undertaking the independent ethical review of a HRE Application or HRE Amendment Application, reviewers will include their feedback for the applicant to address and/or defend via the Page Comments function.

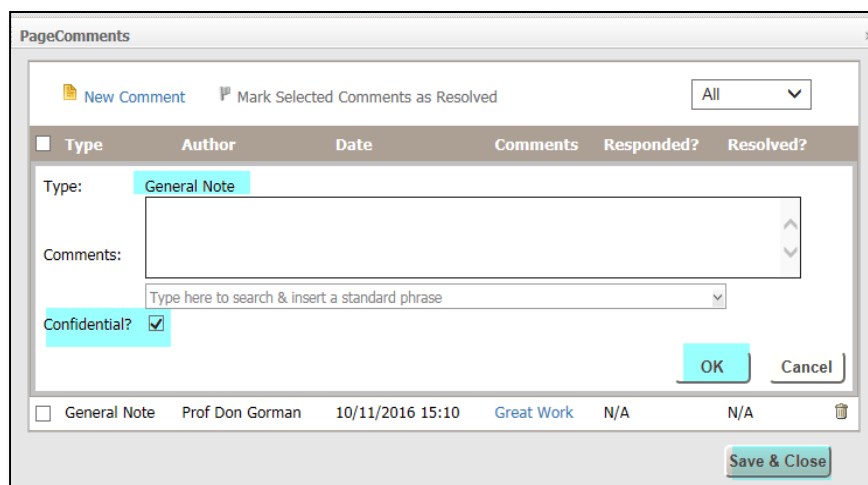
A blue flag  is added to the end of the page heading, and to the section heading (within the left-hand menu) to denote a Page Comment has been added and is available for viewing.



4.1 Adding a Page Comment

All Page Comments added as part of the independent ethical review process must remain confidential.

- Navigate to the page you wish to add the Page Comment to
- Click on the **Page Comment** link




Type	Author	Date	Comments	Responded?	Resolved?
General Note	Prof Don Gorman	10/11/2016 15:10	Great Work	N/A	N/A

- Click on the **New Comment** link
- Enter the question number that the feedback refers to, followed by the feedback. For e.g., 3.5. Please elaborate on your response in this section to identify the method of participant recruitment.
- Ensure that the **Confidential?** has been checked (this should be automatically selected).
- Click the **OK** button.
- Add a separate New Comment for each section on this e-form page.
- Once all comments have been added, click on the **Save & Close** button

4.2 Viewing a Page Comment

- Navigate to the page (to which the Page Comment is attached).
- Click on the **Page Comment** link.
- Click on the link of the comment you wish to view.
- Click on **Save & Close** button.

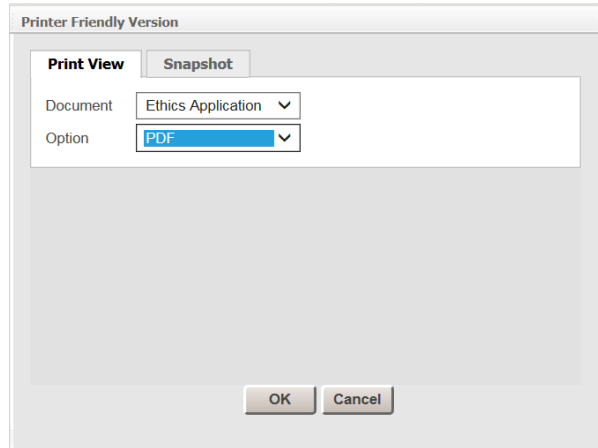
4.3 Deleting a Page Comment

- Navigate to the page (to which the Page Comment is attached).
- Click on the **Page Comment** link
- Click on the  bin button to the right of the Page Comment you wish to delete.
- Click on **Save & Close** button.

5. RIMS Reporting

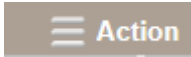





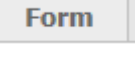
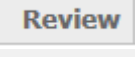
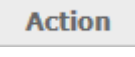






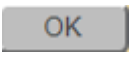
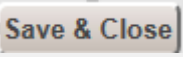
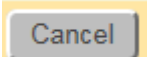




5.1 Ethics Application Report

- Open the desired application
- **Reports | Print View** (tab)



- From **Document** dropdown menu, choose **Ethics Application**.
- From **Options** dropdown menu, choose **PDF**.
- Click on the **OK** button
- The report will may take a few seconds to generate in a new browser window.

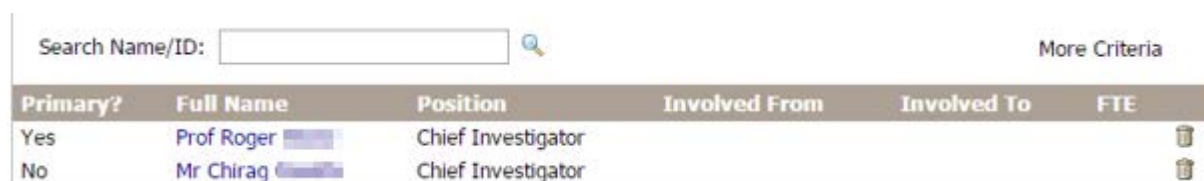
Appendix A - Navigating RIMS e-forms

Symbol	Description	Use it To....
 Action	Action Link is used to undertake actions, such as submit e-form	
 Save	Save Link is used to save an e-form	
 Form Comments	Form Comments are NOT USED AT USQ	
 Page Comments	Page Comments Link is used to access the dialog box to add, view and delete comments. Note: You must be on the correct page within the application to view the page comments.	
 Reports	Reports Link is used to access the reporting functions dialog box.	
 Exit	Exit button is used to close an e-form and return to the Applications page.	
 Form	Form Tab is used to view the HRE application form	
 Review	Review Tab is used for nominating reviews and identifying application outcome	
 Action	Action Tab is used to action the workflow of an application	
 Help	Page Help Link is NOT CURRENTLY USED AT USQ	
	Exit button is used to save and close the e-form.	
 *	Red asterisk denotes a mandatory question	
	Help button is located at the end of questions. This will provide further details about the information required for each specific question. Click on  at top right corner of box to close Help feature.	
	Search Icon	
 OK	OK button is used to commit your changes made to a sub-form grid items. Also used to commit new items to the grid.	
 Save & Close	Save & Close button is used to save your work and close the text box.	
 Cancel	Cancel button is used to cancel changes to a sub-form grid item. Can also be used to cancel the action of adding an item to the grid. Note: once an item has been committed to the grid, the Delete button  must be used to remove the item from the grid.	
	Date Selector used to select a date rather than typing it in	
	Deletes selected record	
	Previous Page and Next Page buttons. Used to navigate between the pages of an e-form	

Appendix B - RIMS Definitions

Grid

Any RIMS information presented in tabular format is referred to as a grid.




The screenshot shows a search interface with a text box for 'Search Name/ID:' and a magnifying glass icon. To the right is a link for 'More Criteria'. Below is a table with columns: Primary?, Full Name, Position, Involved From, Involved To, and FTE. The first row shows 'Yes' for Primary?, 'Prof Roger' for Full Name, 'Chief Investigator' for Position, and a trash icon for FTE. The second row shows 'No' for Primary?, 'Mr Chirag' for Full Name, 'Chief Investigator' for Position, and a trash icon for FTE.

Primary?	Full Name	Position	Involved From	Involved To	FTE
Yes	Prof Roger	Chief Investigator			
No	Mr Chirag	Chief Investigator			

Grid Item

Each individual item within a GRID is referred to as a Grid Item. In the image displayed above, each investigator is a grid item in the Investigators grid.

Sub-form

Adding a new item to a grid causes a sub-form to automatically open up for data entry. The sub-form also opens up when you select an individual grid item (coloured in blue). For example, clicking on Prof Roger Stone's name in the Investigators grid will cause the Investigator sub-form to appear so that you may key in information specific to that investigator. Any modification made in the sub-form must be committed to the grid by clicking on the  button.