Creating a Standard Project Human Ethics Application

A Standard Project application is to be completed for all individual research projects unless they are eligible for consideration as a project involving minimal risk or are part of an existing HREC approved program application. A Standard Project application requires HEAG review and HESC approval.

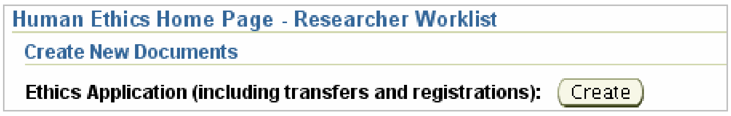
Creating a Standard Project Application

1 Log in to Themis using the **UOM Research Self Service** responsibility.

2 Select the **Human Ethics Workbench** function listed under the Ethics section.

The Human Ethics Home Page - Researcher Worklist screen will display.

3 Click on the **Create** button in the Create New Documents section.



The Project Type screen will display.

Define the Project Type

1 Tick the appropriate checkbox(s) to identify the type of project for which you are applying.

Note: you may select multiple project types, if appropriate.

Project Type	Additional information required
Staff Research Project	No additional information is required on this screen for this option.
Practical Class	You must provide the name of the class in the field that displays below.
Funded Consultancy	No additional information is required on this screen for this option.
Supervised Student Research Project	You must select the appropriate tertiary level/s (e.g.: Doctorate, PhD, Advanced Medical Science, etc.) using the checkboxes in the table that displays below.
Other	You must specify the nature of the application in the field that displays below.

2 Click on the **Next** button.

The Research Checklist screen will display.

Complete the Research Checklist

The information entered in the checklist will determine: the application types available; additional questions to be completed online; and additional modules to be completed offline and attached to the application.

Important: you must select at least one item from the Available Checklist Item list before progressing (choose **None of the above** if applicable). If you do not select any checklist item a warning message will display when you try and progress to the next screen.

1 Highlight the item you wish to add from the Available Checklist Items list (on the left).

Note: the description for the selected item will display in the field under the table.

2 Click on the arrow to move the highlighted item to the Selected Checklist Items list (on the right).

To add all available items to the Selected Checklist Items list at once, click on the arrow, or use the **Move All** hyper-link (remember to remove the **None of the above** item before progressing).

Click on the arrow to remove an item from the Selected Checklist Items list, if required.

3 Click on the **Save as Draft** button.

While you may save the record at any stage of the application process, it is recommended that you save regularly to ensure you do not lose information if your session times out.

4 Click on the **Next** button.

The Application Type screen will display.

Select the Application Type

1 Click on the appropriate radio button (**Standard Project**) to identify the application type.

The following step in the process will vary depending on the application type selected here.

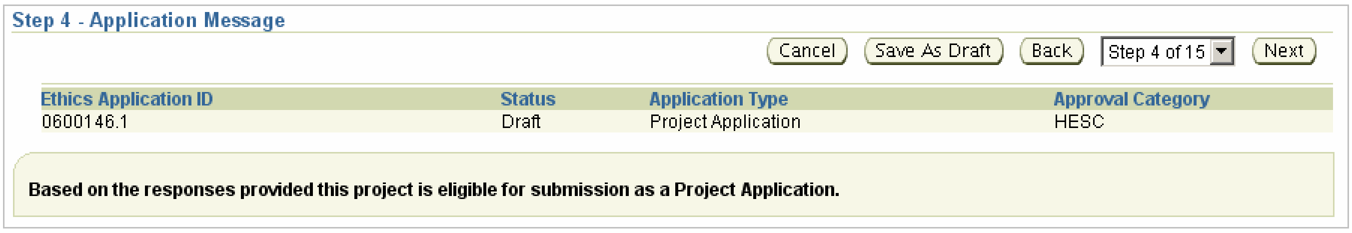
Application Type	Process
Minimal Risk	You must complete further checklists before proceeding to the Application Message screen.
Standard Project	You may proceed directly to the Application Message screen.
Program	You must confirm that you are seeking approval for a broad program of research within which individual projects can be identified to be part of the program before progressing to the Application Message screen.
Project Within a Program	You must specify the HEAG and the program (or add the program) and confirm that you have read the approved program application before proceeding to the Application Message screen.
Transfer of Ethics Clearance	You may proceed directly to the Application Message screen.
Registration of External Ethics Clearance	You may proceed directly to the Application Message screen.

2 Click on the **Next** button.

The Application Message screen will display.

Application Message Screen

Once Themis collates and evaluates all the information you entered in the relevant checklists and project type screens, the Application Message screen will display a message of eligibility for the Human Ethics application project type.



1 Click on the **Next** button.

The Project Details screen will display.

Enter the Project Details

The Project Details screen allows you to identify the responsible HEAG and enter information relating to your application (i.e.: project title, description and dates).

1 Enter the Project Details.

Field	Action	Comments
Responsible HEAG	Select the appropriate HEAG from the drop-down list	
HESC	This field will default based on the HEAG selected above	
Project Title	Enter the title of your project	
Brief description of project	Enter a brief description of the project	The description, no more than 100 words, should outline the broad aims and key questions of the project.
Project From date	Use the drop-down list to select the month and year the project is expected to start	
Project To date	Use the drop-down list to select the month and year the project is expected to end	
Start date for data collection phase	Enter the proposed start date for the data collection phase of the project	**Important:** data collection may not commence until formal approval for the project has been granted and the date entered in this field should allow for a reasonable period of review of your application.

2 Click on the **Next** button.

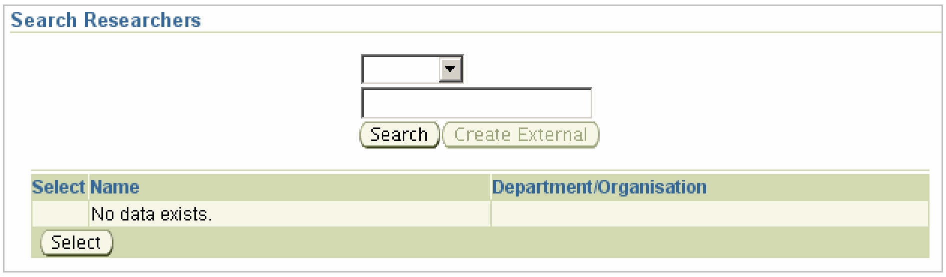
The Participating Researcher screen will display.

Enter the Participating Researchers

The Project Details screen allows you to record the researchers associated with your project, the role they will take in the research, as well as their contact, qualification and relevant training details.

1 Click on the **Add Researcher** button.

The Search Researchers screen will display.



2 Select the category of researcher for which to search from the drop-down list in the top field.

- Select **Staff** if the researcher is a member of staff at the University of Melbourne.
- Select **Student** if the researcher is a student at the University of Melbourne.
- Select **External** if the researcher belongs to an external organisation or is retired.

3 Enter the surname of the researcher for which you are searching in the bottom field.

4 Click on the **Search** button.

A list of researchers matching your search criteria will display in the table below. **Note:** if no data is returned for an External researcher you may create an external person record (refer to **Creating an External Researcher in Human Ethics** information sheet).

5 Click on the radio button in the Select column to select the appropriate researcher then click on the **Select** button.

The Researcher Details screen will display.

Enter the Researcher Details

You must complete the information in the Researcher Details screen for each researcher you add to your ethics application.

6 Enter the researcher details.

Field	Action	Comments
Name	Field will default from the Themis record	
Phone Number	Field will default from the Themis record	
Researcher Role	Select the appropriate role from the drop-down list	For further information on the available roles refer to the table on page 7.
Researcher Type	Field will default from the Themis record	
Department	Field will default from the Themis record	
Centre (if applicable)	Use the Search and Select function to retrieve the appropriate Centre	This field should be left blank if the researcher does not belong to a Centre. **Note:** the list of available Centres only includes formal University Centres created under Regulation 6.1.R7.
Contact Details fields	Enter alternate contact details if required	**Note:** these contact details will be stored against the ethics application and will not be available on the person's Themis HR record.
HR Validated Qualifications	This field will display any qualifications that a staff member has entered via Themis Self Service	
Additional Qualifications	Enter any additional qualifications not displayed above	
Experience and Skills relevant to the project	Enter any experience the researcher has that is relevant to the project	This field is mandatory. In particular, you should describe any experience the researcher or supporting staff has in conducting research of this type and in dealing with any emergencies, unexpected outcomes or contingencies that may arise.
Additional training required	Enter any additional training required to carry out this research	This field is optional. **Note:** you should include details on how training identified will be provided.
Ethics training already undertaken	Enter details of any ethics training the researcher has undertaken that will benefit this research	This field is mandatory for student researchers.

7 Click on the **Save and Continue** button.

The Participating Researcher screen will display, and the researcher you have added will display in the researcher table.

Select	Researcher Role	Researcher Type	Researcher Name	Department/Organisation
○	Responsible Researcher	Staff	Ball, Ms Crystal	University Systems Project

Add Researcher | Delete Researcher | Update Researcher

8 Follow **steps 1 to 7** above to enter additional researchers if required.

Note: for any project there must be one and only one Responsible Researcher named against the project.

9 Once you have added all the required researchers, click on the **Next** button to continue.

The Additional Documentation Required screen will display.

Access Additional Documentation

The Additional Documentation Required screen will display any forms that you must complete and attach to your ethics application prior to submission. The forms are available on the Research Office web site but you will be able to download them via the hyperlink/s on this screen. Refer to the **Human Ethics - Table of Research Checklist Items** document for a complete list of documentation required for each application type.

1 **Important:** Click on the **Save As Draft** button before proceeding to download any additional documentation.

A confirmation message will display advising that the application has been saved.

2 Click on the hyperlink for the form you wish to download.

The link will access the relevant document from the Research Office web site and open it in a new browser window. In most cases the document will open at an instruction sheet, and you will need to scroll down from this page to view the body of the form.

3 Save the document to your PC/local server for later completion and attachment to Themis.

4 Close the browser window and reactivate your Themis session.

5 Complete **steps 2 to 4** above for all required documents.

6 Once you have accessed all the required documents, click on the **Next** button to continue.

The Attachments screen will display.

Attach Required Documentation

The Attachments screen allows you to attach any relevant documents to your Human Ethics application (including: the full application, consent forms, plain language statements and additional statements). This screen also allows you to log details of any documentation that can only be provided in hard copy.

Add an electronic attachment

1 Click on the **Add Attachment** button in the Attachment table.

The Add Attachment screen will display.

2 Complete the attachment details.

Field	Action	Comments
Add	Field will default to **Desktop File/Text/URL**, do not change	
Description	Enter a brief description of the attachment	This field is mandatory.
Category	Select the category of the attachment from the drop-down list	Categories available are: **Additional Module**, **Advertisement**, **Application**, **Consent Form**, **Debriefing Statement**, **Interview**, **Miscellaneous**, **Plain Language Statement**, and **Test**. **Note:** you must include an attachment in the Application category before you will be able to submit the ethics application for review.
Type	Click on the radio button to select the appropriate attachment type	**If selecting File**: click on the **Browse** button to locate and select the document you wish to attach. **If selecting URL**: type the full internet address you wish to reference. **If selecting Text**: enter a simple text message in the field provided. If desired you may enter a name for the text attachment in the field below.

If you wish to add multiple attachments, go to task # 3. Otherwise go to task #4.

3 Click on the **Add Another** button and repeat **step 2** for each new attachment.

4 Once you have added all your attachments click on the **Apply** button.

You will receive a confirmation that the attachment has been added but not saved.

5 Click on the **Save As Draft** button to save the attachment.

Register a document to be provided in hard copy only

1 Click on the **Add Another Row** button in the Supporting Documents table.

The Add Attachment screen will display.

2 Complete the document details.

Field	Action	Comments
Attachment Type	Select the category of the attachment from the drop-down list	Categories available are: **Additional Module**, **Advertisement**, **Application**, **Consent Form**, **Debriefing Statement**, **Evidence of Approval**, **Interview**, **Other**, **Plain Language Statement**, and **Questionnaire/Survey**.
Description	Enter a brief description of the document you will be submitting	

3 Repeat **steps 1 and 2** for each document you wish to register.

4 Once you have registered all your attachments click on the **Save As Draft** button.

You will receive a confirmation that the application has been saved.

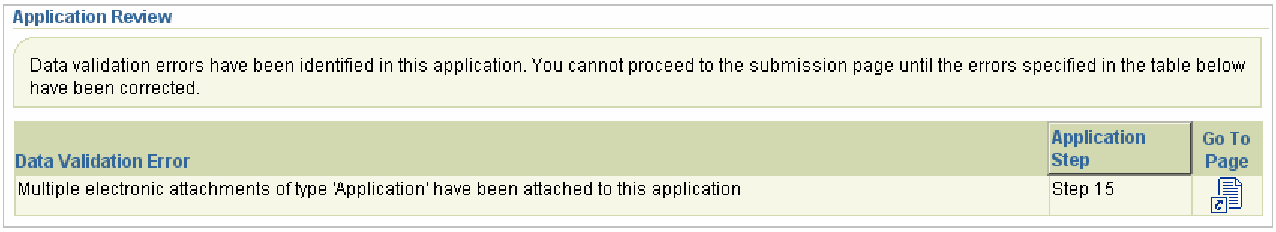
5 Once you have attached all the required documents, click on the **Next** button to continue.

The Application Review screen will display.

Review the Application

The Application Review screen will identify any validation errors or omissions (e.g.: either not including an Application type attachment or identifying multiple Application type attachments) in relation to your ethics application.

If validation errors are identified



1 Click on the associated icon in the Go To Page column.

This will link you directly to the appropriate page.

2 Update the information as required and click on the **Save As Draft** button to commit your changes.

3 Use the drop down list (Validation Page) at the bottom of the screen to return to the review page.

4 Repeat **steps 1 to 3** above for each of the validation errors.

5 Click on the **Next** button.

The Submission screen will display.

Submit the Application

Once you have reviewed your application and corrected any validation errors, you may submit your application for review by the nominated HEAG.

1 Read the submission confirmation statement.

2 Tick the checkbox to the right of the statement.

Note: you will be unable to submit the application until you tick this box (i.e.: the **Submit Application** button will not be active).
Important: if someone other than the responsible researcher submits the application, additional checkboxes will display and must be answered before you will be able to submit the application.

3 Click on the **Submit Application** button.

A Confirmation of Submission screen will display.
Note: all researchers named on the application will receive an email to confirm the application has been submitted for review and the application will display in the **Current Applications** section of the Human Ethics Worklist, with a status of Submitted. Any of the named researchers (with access to Themis) will be able to view the application and track its status via their Worklist.

Print the Application

Once you have submitted your application in Themis, you will need to print a copy of the application summary report and submit it with any the required number of copies of your supporting documentation to the nominated HEAG. **Note:** for details instructions refer to the **Printing a Human Ethics application and related attachments** information sheet.

1 Click on the **Reporting** tab located on the top right of the screen.

The Submit Report screen will display.

2 Enter your report specifications.

Field	Action	Comments
Report Name	Select **UOM RMS HE AP XXX - Application Summary** from the drop-down list	**Note:** replace **XXX** with the application type you wish to print (e.g.: Project Application, Project Application, Request for Transfer, etc).
Description	Enter a description for the report, if desired	**Note:** this field is optional, but entering a description may help you identify the report later.
Application Version	Enter the application version number of the application you wish to print, or use the **Torch** to select from the list of values	**Note:** you will only be able to select from the ethics applications on which you are named as a researcher or for which you are responsible as a HEAG administrator.
Format	Select the desired report format from the drop-down list	This field will default to **PDF**, but if you would like the output in a form that you may edit, select **RTF** (word).

3 Click on the **Submit** button.

A message will display advising that your report has been scheduled, and indicating the request ID number. Click **OK** to close this message. The Requests monitoring screen will display.

4 Click on the **Output** icon to open the application in the web browser screen.

5 Select **File > Print** from the web browser Toolbar to print the application.

6 Ensure the application is signed by all responsible researchers.

7 Submit the paper copies of your application and any attachments to the HEAG Administrator.

The paper copy you submit to the HEAG Administrator must contain the following documents:

- the application summary (data entered directly into Themis)
- the completed application form (the document electronically attached via Themis)
- other attachments (either electronically attached via Themis or being provided in hard copy only - including plain language statements, consent forms, etc)

Definition of Researcher Roles

Researcher Role	Researcher Role Definition
Responsible Researcher	For any project there must be a Responsible Researcher named against the project. **Note:** there may only be one person with this role per application and only a member of staff may be named. In the case of Student Projects, please note the Responsible Researcher would be the student supervisor (even in the case of PhD projects). Only the person named as Responsible Researcher, and the creator, will have access to update an application.
Student Researcher	There can be multiple student researchers associated with a project. It is recognised that for many projects, the Student Researcher is the person who is actually conducting the research and may be submitting the application.
Co-researcher	There can be multiple Co-researchers associated with a project. These would normally be persons in the role of co-supervisor of a student project, or other contributing researchers (staff or external).
Associated Personnel	There can be multiple associated personnel with a project. This role would only be assigned to a person who is not considered a researcher on the project.