Creating an Animal Ethics application

An animal ethics application is to be completed for all research projects involving animals.

Important: it is recommended that, while completing your animal ethics application, you save regularly to ensure you do not lose information if your session times out.

Creating an application

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

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

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

3 Click on the **Create** button (Ethics Application) in the Create New Documents section.

The Application Type screen will display.

Define the application type

1 Select the appropriate type of application from the drop-down list.

Application Type	When to use
Research Application	To seek approval for use of animals in a research project.
Teaching Application	To seek approval for use of animals in a teaching project.

2 Click on the **Next** button.

The Project Overview screen will display.

Enter the course details (teaching projects only)

The Project Overview screen allows you to identify the course to which the project is attached.

1 Enter the course details.

Field	Action	Comments
Course/Subject Code	Enter the code for the course or subject to which the project is attached	

Enter the project overview

The Project Overview allows you to identify the Scientific Procedures Premises Licence (SPPL) under which the research falls and project details.

1 Enter the project details.

Field	Action	Comments
Scientific Procedures Premises Licence	Select the appropriate SPPL from the drop-down list	
Licence Number	This field will default based on the SPPL selected above	
Responsible AEC	This field will default based on the SPPL selected above	
Title	Enter the title of your project	Your title should be concise and expressed in lay language (max. 500 characters). You may use the formatting toolbar to format your title and/or include special characters.
Proposed Commencement Date	Enter the proposed start date for your project	**Important:** the date must not be before the meeting of the relevant AEC. Scientific activities must not commence until written approval for the project has been granted.

2 Click on the **Next** button.

The Funding and Contracts screen will display.

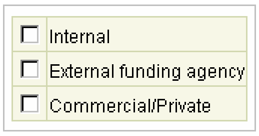
Enter the funding and contract details (research projects only)

The Funding and Contracts screen allows you to indicate the source of funding for the project as well as any contracts associated with the research.

Identify the principal source of funding for this project:

1 Tick the checkbox/s for the project's principal source of funding.

Note: you may select multiple sources, if appropriate.



Is this project Commercial in Confidence?

2 Click on the appropriate radio button to indicate whether the project is commercial in confidence.

Is this project covered by a research contract?

3 Click on the appropriate radio button to indicate whether there are any associated research contracts.

4 Click on the **Next** button.

The Risk Management screen will display.

Enter the risk management details

The Risk Management screen allows you to indicate any risks to other animals and/or researchers associated with the project.

Does the research involve procedures or agents that might pose a health risk to other animals and/or personnel?

1 Click on the appropriate radio button to indicate whether there is any risk to animals or researchers.

Note: if you select Yes you will need to complete additional information that displays below.

If you have selected Yes go to task #2. Otherwise go to task #3.

2 Enter the details of the risks and precautions that will be taken (max. 2000 characters).

Is the acquisition, holding, or use of the animals subject to any permit, law or regulation of the State or Commonwealth?

3 Click on the appropriate radio button to indicate whether the project is subject to a permit, law or regulation.

Note: if you select Yes you will need to complete additional information that displays below.

If you have selected Yes go to task #4. Otherwise go to task #5.

4 Enter the details of the permit number/s (max. 500 characters).

5 Click on the **Next** button.

The Project Summary screen will display.

Enter the project summary details

The Project Summary screen allows you to enter the background, aims and summary of the project/course.

Note: Information should be entered in language that can be understood by an interested, intelligent person without a scientific background.

1 Enter a brief discussion of the background of the project/course (max. 4000 characters).

The information in this field should also include a description of how this project relates to any previously approved project/course.

2 Enter the aims of the project/course (max. 2000 characters).

3 Provide a brief outline explaining how the project/course is designed in relation to its aim, outlined above (max. 4000 characters).

The information in this field should also include an overview of what will happen to the animals upon completion of the project/course.

4 Click on the **Next** button.

The Justification screen will display.

Enter the project justification details

The Justification screen allows you to specify the potential benefits of the project, any impact on the animals and details of previous related work or previous use of the animals selected.

Potential Benefit

1 Enter an explanation for the significance and potential benefits of your proposed project/course (max. 3000 characters).

Potential Impact on the Animals

2 Enter details outlining the degree of pain or distress to be experienced by the animals (max. 3000 characters).

The information in this field should also include a reason for this assessment.

Repeated Studies

3 Click on the appropriate radio button to indicate whether your project duplicates work already carried out.

Note: if you select Yes you will need to complete additional information that displays below.

If you have selected Yes go to task #4. Otherwise go to task #5.

4 Enter the details of previously undertaken work (max. 3000 characters).

Repeated Use of Animals

5 Click on the appropriate radio button to indicate whether the animals have been used in previous scientific or teaching activities.

Note: if you select Yes you will need to complete additional information that displays below.

If you have selected Yes go to task #6. Otherwise go to task #9.

6 Click on the **Add Another Row** button.

A blank row will display.

7 Enter the details of the previous use.

Field	Action	Comments
Ethics ID	Enter the ID number of the relevant ethics application/approval	
Approving Institution	Indicate whether the approval was granted by the **University of Melbourne** or **Other** institution by selecting from the drop-down list	**Note**: if you select Other you must enter the name of the institution in the field below.
Other Institution	Enter the name of the approving institution, if not University of Melbourne	

8 Enter the details of previous work and justification for use of the animals in your current project/course (max. 3000 characters).

9 Click on the **Next** button.

The Glossary of Scientific Terms screen will display.

Enter definition of any scientific terms

The Glossary of Scientific Terms screen allows you to provide a lay description for any scientific terms/language you have used in your animal ethics application.

1 Click on the **Add Another Row** button.

A blank row will display in the Glossary of Terms table.

2 Enter the details of the scientific term.

Field	Action	Comments
Scientific Term	Specify the scientific term used in the ethics application	
Lay Description	Enter a description in language that can be understood by a person without a scientific background	

3 Repeat steps 1 and 2 above for each term you wish to add.

4 Click on the **Next** button.

The Replacement, Reduction, Refinement screen will display.

Enter the replacement, reduction and refinement details

The Replacement, Reduction, Refinement screen enables you indicate that you have considered your research/teaching in light of replacing or reducing the number of animals used as well as refining your research techniques to reduce impact on the animals.

Replacement

1 Click on the appropriate radio button to indicate whether you have incorporated alternatives that replace the use of animals in your project.

2 Enter details to further explain your response (max. 2000 characters).

- If you entered No, you must identify the potential alternatives and explain why they are unsuitable for your project
- If you entered Yes, you must identify the alternatives that are being used in your project

Reduction

3 Enter an explanation for the number of animals being requested for your project (max. 4000 characters).

Your explanation should be based on statistical analysis and/or other considerations of your experimental design.

4 Click on the appropriate radio button to indicate whether the animals or their tissue could be used in another project.

5 Enter details to further explain your response (max. 2000 characters).

- If you entered Yes, you must provide further details and identify the suitable project, if known
- If you entered No, you must enter an explanation for why they would not be suitable

Refinement

6 Enter an explanation for your choice of animal (max. 4000 characters).

Your explanation should include reference to species, strain, sex and age of the animals you have selected.

7 Click on the **Next** button.

The Animals Requested screen will display.

Enter details of the animals requested

The Animals Requested screen enables you to record the details of all animals that you will use in your project/course (including their source and housing arrangements).

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

The Animal Details screen will display.

2 Enter the animal details.

Field	Action	Comments
Category	Select the category of animal from the drop-down list	The category you select will determine the contents of the drop-down list for following fields.
Type/Species	Select the type or species of animal from the drop-down list	The category you select above will determine the values that display in this list.
Breed/Strain	Select the breed or strain of animal from the drop-down list	The type/species you select above will determine the values that display in this list.
Strain Name	Enter the name of the animal strain, if not available in the list above	This field will only display if you select Specify Strain Name in the Breed/Strain field above.
Age	Enter the age of the animals being used in the project/course	This field is free text so you may enter an age range if appropriate.
Sex	Select the sex of the animals being used in the project/course from the drop-down list	
Total Number Requested	Enter the total number of animals you are requesting for use in the project/course	
Source	Select the source for where you will obtain your animals from the drop-down list	**Note:** if you specify Other, you will need to enter details in the Other Source field that displays below.
Housing	Select the location that you will be housing the animals from the drop-down list	**Note:** if you specify Other, you will need to enter details in the Other Housing field that displays below.

3 Click on the appropriate radio button to indicate whether your research involves animals with spontaneous genetic mutations or genetically modified animals.

Note: if you select Yes you will need to complete additional information that displays below.

If you have selected Yes go to task #5. Otherwise go to task #4.

4 Click on the appropriate radio button to indicate whether your research uses or produces cloned animals.

Note: if you select Yes you will need to complete additional information that displays below.

If you have selected Yes go to task #5. Otherwise go to task #16.

Genetic Modification or Cloning of Animals

5 Enter information regarding the background strain of animals selected.

Genotype

6 Enter information regarding the functions of the gene/s that you have or will modify.

7 Enter information regarding the relevance of the modification to your project.

8 Select from the drop-down list to indicate whether you will be collecting tissue to use in genotyping.

Note: if you select Yes you will need to complete additional information that displays below.

If you have selected Yes go to task #9. Otherwise go to task #10.

9 Enter the details of how and when you will be collecting tissue.

10 Enter information regarding the fate of animals not of the appropriate genotype.

Phenotype

11 Select from the drop-down list to indicate whether the phenotype of the strain is well characterised.

12 Enter details to further explain your response.

- If you entered Yes, describe the features of the strain and how the modifications will affect the animals
- If you entered No, describe the anticipated features of the strain and if the modifications will affect the animals

13 Select from the drop-down list to indicate whether the strain will require any special husbandry.

If you have selected Yes go to task #14. Otherwise go to task #15.

14 Enter details to describe the special care requirements.

Breeding

Note: you should only complete this section if the animals are being bred in-house

15 Describe the Standard Operating Procedures that describe the breeding program for animals used in your project/course.

Note: you may attach a document outlining the Standard Operating Procedures, if available. Refer to the **Attach Required Documents** section below for further details.

16 Click on the **Save and Continue** button to save the animal record and return to the Animals Requested screen.

17 Repeat steps 1 to 16 above for each animal you wish to add.

18 Once you have added all the animals your require, click on the **Next** button.

The Transport and Location of Animals screen will display.

Enter details of the transport and location of the animals

The Transport and Location of Animals screen enables you to record the arrangements you have made for transport and housing of animals being used in your project/course.

Transport of Animals

1 Click on the appropriate radio button to indicate whether you will need to transport animals from their source location to where they will be housed.

Note: if you select Yes you will need to complete additional information that displays below.

If you have selected Yes go to task #2. Otherwise go to task #3.

2 Enter the details of your transportation and acclimatisation procedures (max. 2000 characters).

3 Enter the details of where your research will be performed (max. 2000 characters).

You should also include any details of transportation and acclimatisation procedures if you will be transporting the animals from their housing facility to your research location.

Location of Animals and Housing

4 Click on the appropriate radio button to indicate whether you will be housing the animals outside.

Note: if you select Yes you will need to complete additional information that displays below.

If you have selected Yes go to task #5. Otherwise go to task #6.

5 Enter the details of the shelter you will be providing (max. 2000 characters).

If you will not be providing shelter, or it is contrary to the needs of the species, you must provide further details to justify your arrangements.

6 Enter the details of the housing you will be using for the research period (max. 2000 characters).

You should also include any special housing requirements.

7 Click on the appropriate radio button to indicate whether you will be housing the animals individually.

Note: if you select Yes you will need to complete additional information that displays below.

If you have selected Yes go to task #8. Otherwise go to task #9.

8 Enter further details explaining these arrangements, how long they will be in place and how you will minimise the impact of social isolation (max. 2000 characters).

You should include an explanation as to why you will be housing the animals individually, for how long, and how you will minimise the impact of social isolation.

9 Click on the **Next** button.

The Project Description screen will display.

Enter a description of your project

The Project Description screen enables you to explain the scientific rationale of your project and provide a detailed description of your experimental design.

1 Enter details of your project.

2 Click on the **Next** button.

The Details of Personnel Involved in the Project screen will display.

Enter the details of personnel involved in your project

The Personnel Involved in the Project screen enables you to record all people involved in your project/course (including researchers, students, and animal facility staff) their experience working with animals as well as any training and/or supervision required.

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

The Personnel Search screen will display.

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

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

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

4 Click on the **Search** button.

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

Select	Name	Department/Organisation
○	BALL, MS CRYSTAL	018-University Systems Project
Select		

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

The Personnel Details screen will display.

Enter the Person Details

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

6 Enter the person details.

Field	Action	Comments
Name	Field will default from the Themis record	
Phone Number	Field will default from the Themis record	
Role	Select t he appropriate role from the drop-down list	**Note:** if you select "Animal Facility Manager" you will need to complete the Animal Facility field below. For further information on the available roles refer to the table below.
Person Type	Field will default from the Themis record	
Primary Contact	Tick this box if the person is to be the primary contact for the project/course	**Note:** you may only specify one primary contact per application. The primary contact must be a member of staff of a student of the University and must have an email and telephone contact in the Personal Details section. This will be the person who will always receive any email advice regarding the approval process.
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 person does not belong to a Centre. **Note:** the list of available Centres only includes formal University Centres created under Regulation 6.1.R7.
Animal Facility	Select the appropriate facility from the drop-down list	
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 student or external personnel qualifications or staff qualifications not displayed above	

Enter the Person's Involvement in the Project

7 Click on the **Add Another Row** button.

A blank row will display in the table.

8 Enter the person's experience details.

Field	Action	Comments
Species	Select the appropriate specie from the drop-down list	The contents of this list will be determined by the details entered in the Animals Requested screen.
Technique/Procedure	Enter the technique or procedure the person will be undertaking	
Number of times person has performed technique/procedure on species selected	Select the appropriate value from the drop-down list	**Note:** if you select a value of "0" the Training Required field will default to "Yes".
Training Required	Select Yes or No from the drop-down list to indicate whether training is required for the nominated procedure	**Note:** this field will default to "Yes" if you select "0" in the above field.
Training Provided By	Enter the name of the person who will be undertaking the training	
Expertise of Trainer	Enter details outlining the experience/expertise of the nominated trainer	

9 Repeat steps 7 and 8 for each animal listed in relation to the project.

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

The Details of Personnel Involved screen will display, and the person you have added will display in the personnel table.

11 Follow steps 1 to 10 above to enter additional people if required.

Note: for any project there must be one and only one Project Supervisor named against the project.

12 Once you have added all the people you require, click on the **Next** button to continue.

The Monitoring screen will display.

Enter the monitoring details

The Monitoring screen enables you to enter details regarding how you will assess any impact on the animal's welfare. **Important:** Unexpected incidents that impact on the welfare of any individual animal or group of animals require an immediate response and must be reported to the AEC via the Executive Officer, Animal Ethics Office.

Who will monitor the animals - Weekdays?

1 Click on the **Add Weekday Monitor** button in the Weekdays table.

A blank row will be added to the table.

2 Select the appropriate person from the drop-down list.

Note: this list will display all people recorded in the Details of Personnel Involved screen. If the appropriate person is not listed, return to **Step 11 - Details of Personnel Involved in the Project** and add the person to your application record.

3 Repeat steps 1 and 2 for each person you wish to add.

Who will monitor the animals - After Hours?

4 Click on the **Add After Hours Monitor** button in the After Hours table.

A blank row will be added to the table.

5 Select the appropriate person from the drop-down list.

Note: this list will display all people recorded in the Details of Personnel Involved screen. If the appropriate person is not listed, return to **Step 11 - Details of Personnel Involved in the Project** and add the person to your application record.

6 Repeat steps 4 and 5 for each person you wish to add.

Monitoring details

7 Enter the details of the day-to-day monitoring you will undertake during your project (max. 1000 characters).

You should include the specific signs you will monitor and how frequently they will be monitored.

8 Enter the details monitoring you will undertake during and after procedures (max. 1000 characters).

You should include the specific signs you will monitor and how frequently they will be monitored.

9 Enter the details of the signs used to indicate whether intervention is required (max. 3000 characters).

You should include details of the action to be taken if you observe these indicators.

Management of emergencies

10 Click on the **Add Emergency Manager** button.

A blank row will be added to the table.

11 Select the appropriate person from the drop-down list.

Note: this list will display all people recorded in the Details of Personnel Involved screen, but you may enter an alternative person not recorded in this list.

If you have selected Other go to task #12. Otherwise go to task #13.

12 Enter the name of the emergency manager.

13 Click on the **Next** button.

The Fate of Animals screen will display.

Enter the fate of the animals

The Fate of Animals screen enables you to enter details regarding the fate of the animals you are using in your research project.

1 Enter the maximum period of time that an animal will be used in your project (max. 1000 characters).

2 Enter details outlining what will happen to the animals when you complete your project (max. 1000 characters).

3 If the animals are to be killed, enter details about the process to be undertaken (max. 2000 characters).

You should include information about agents, dose rates, method and experience of personnel undertaking this process.

4 Enter details for the method of disposal of the animals (max. 1000 characters).

5 Click on the **Next** button.

The Attachments screen will display.

Attach required documentation

The Attachments screen allows you to attach any relevant documents to your Animal Ethics application (including: extension information in response to application questions). This screen also allows you to log details of any documentation that can only be provided in hard copy.

Important: you must include an attachment in the Monitoring Checklist category before you will be able to submit your application. If you feel you have a legitimate reason for not attaching a Monitoring Checklist, select an attachment Type of TEXT and describe what you will be doing. This will satisfy the requirements of the attachment validation step.

Summary of electronic documents

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: **Extension to question in application**, **Monitoring Checklist Proforma**, and **Miscellaneous**.
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.

Summary of supporting documents provided in hard copy only

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

A blank row will display.

7 Complete the document details.

Field	Action	Comments
Attachment Type	Select the category of the attachment from the drop-down list	Categories available are: **Extension to question in application**, **Monitoring Checklist Proforma**, and **Other**.
Description	Enter a brief description of the document you will be submitting	

8 Repeat steps 6 and 7 for each document you wish to register.

9 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.: not nominating a project supervisor) 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 (located at the top and bottom) of the screen to return to the review page.

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

5 Click on the **Next** button.

The Declaration and 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 appropriate people before it will be considered by the AEC.

The Declaration and Submission page will display the people who must sign-off your application.

Based on details included in this application, sign-off is required by the following BEFORE the application can be considered by the AEC.

PROJECT SUPERVISOR

HODGKIN, MS REBECCA	018 - University Systems Project	rhodgkin@unimelb.edu.au

INVESTIGATORS

KIDDELL, MS ELISSA	018 - University Systems Project	elissa@unimelb.edu.au

ANIMAL FACILITY MANAGER(S) (person/s named below will be notified unless alternate Animal Facility Manager/s is selected)

ARNETT, MS JENNIFER	018 - University Systems Project	jmarnett@unimelb.edu.au	If necessary, select preferred alternate person with this responsibility.

HEAD OF DEPARTMENT (default named person will be notified unless an alternate person with relevant responsiblity is selected)

JULIAN, MR JOHN	018 - University Systems Project	jcjulian@unimelb.edu.au	If necessary, select alternate approver.

The people listed in this section are determined by the people you entered in the Personnel Involved in the Project section of your application. However, you may you may elect to send the application to an alternate Animal Facility Manager and/or Head of Department. The application will then be sent to the alternate person *instead* of the default person.

To nominate an alternate person to sign-off, click on the **Torch** icon and search for the required staff member in the list of values.

Confirmation statements

1 Read the submission confirmation statement/s.

2 Tick the checkbox to the right of the statement/s.

Note: you will be unable to submit the application until you tick the box/s (i.e.: the **Submit Ethics Application** button will not be active).

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

A Confirmation of Submission screen will display.
Note: all investigators/teachers named on the application and required to sign-off, will receive an email to confirm the application has been submitted for review.