This Animal Ethics Application Guidance document should be used as a companion document whilst completing an Animal Ethics Application. It will provide you with guidance on how to complete your application form and offers examples on the content you should include.

HOW TO USE THE APPLICATION GUIDANCE DOCUMENT

1. This document is designed to be opened at the same time as completing your application form.
2. This document has a ‘Menu’ on the left hand side window that contains links to specific guidance information for each section of the application form.
3. Click on the Section Number you require guidance for and you will be directed to the relevant section of this guidance document.

Example of Section 6 of Animal Ethics Application Form

Example of Section 6 of Application Guidance Document

WHAT TO DO WHEN YOU HAVE COMPLETED YOUR APPLICATION

1. Ensure you have checked your application against the ‘Animal Ethics Application Checklist’ to ensure you have not missed any vital information.
2. It is highly recommended that you have your application pre-reviewed by a trusted colleague experienced in preparing animal ethics applications prior to submission.
3. Save your application as a Microsoft Word file (not a PDF) using the Ethics ID number generated by Themis as the file name.
4. Upload your application into Themis as attachment type “Application”.
5. Upload any Monitoring and Intervention sheets as attachment type “Monitoring and intervention proforma”. Upload any other attachments as attachment type ‘Miscellaneous’. Ensure all attachments are named clearly and logically.
RESPONSIBILITY OF THE APPLICANT

1. Applicants should familiarise themselves with all relevant guidelines and legislation, including the Australian code for the care and use of animals for scientific purposes 8th edition (2013).

2. To ensure that all AEC members are provided with sufficient information to participate effectively in the assessment of the application, all responses must be given in plain English.

3. Responses should be clear and concise, and unnecessary or repetitive information should be avoided.

4. It is highly recommended that prior to submission, you discuss your application with the Animal Welfare Officer and/or a University Animal Ethics Officer and/or your Animal Facility Manager and/or a trusted colleague with experience in the preparation of animal ethics applications. This is especially recommended for principal authors of new applications who have not previously engaged with the University of Melbourne animal ethics system.

RESPONSIBILITY OF THE ANIMAL ETHICS COMMITTEE

1. The primary responsibility of the Animal Ethics Committee is to weigh up the value of the research against the welfare of the animals. This involves ensuring:
   - That the use of animals has scientific or educational merit, and aims to benefit humans, animals or the environment;
   - The number of animals involved in the project is minimised, as is any pain and distress to the animals; and
   - The researchers involved in the project have the skills and experience to do the research.

2. The AEC needs to know:
   - Why you are doing the work
   - What happens to the animals
   - How your application is ethically justifiable according to the requirements of The Code

3. The Committee requires additional justification for activities that involve:
   (a) Severe compromise to animal wellbeing, and for which Replacement, Reduction and Refinement (the 3Rs) cannot be fully applied for the project to proceed, including:
      - Unrelieved pain and distress, including where the planned endpoints will allow severe adverse effects to occur (see Clauses 1.12 and 3.1.18–3.1.19 of The Code)
      - Death as the endpoint (see Clause 1.13 of The Code)
      - Reuse and repeated use of animals (see Clauses 1.22–1.24 and 2.3.15 of The Code)
      - Prolonged restraint or confinement (see Clause 3.3.4 of The Code)
   (b) Use of non-human primates
1. ADMINISTRATIVE DETAILS

1.1 Ethics ID No:
Provide the unique identification number assigned by Themis when the application was created.

Project Title:
The title should give a clear, concise indication of the work proposed.

2. PROJECT BACKGROUND & AIMS

2.1 Provide a plain English summary of the background to the proposed work.
The project summary should explain why you are doing the work. It should include the background/context of the project, and must be expressed in plain English that is readily understandable to an interested, intelligent person without a scientific background.

2.2 Outline the overall aim and any specific aims of the proposed work.
Outline the overall aim of the proposed work as well as any specific aims.

2.3 If applicable, provide details of the relationship of the proposed work to other work, e.g. AEC approved research or teaching, and clinical or agricultural activities.
Include, as relevant, application ID numbers.

3. EXPERIMENTAL OR COURSE DESIGN

Provide the details of your proposed research or teaching activity. It should be clear and concise, but must contain enough detail that a proper assessment of the impacts of the protocols/procedures on each animal (or group of animals) can be made.

This section is designed to be answered in whatever format the applicant feels best explains the work, but should clearly describe what happens to the animals. The Committee is interested in all procedures to be carried out on the animals, and will want to know the extent to which the proposed work might cause discomfort, pain or death. The Committee appreciates that this cannot always be predicted conclusively, however, there must be sufficient information for the Committee to assess the impact of all procedures on the animals. Flow charts or time-lines detailing chronological steps of exactly what is going to be done to the animals and the duration of the procedures help assess the impact of these procedures on the animals.

In general:
- Information should be presented in a logical sequence.
- Information should be structured under relevant headings and subheadings.
- Graphs, tables, timelines and diagrams can be included to help describe your proposal.
- Descriptions or definitions of complex scientific terms and abbreviations should be provided in the Glossary.

This section should include, but is not restricted to, information covering the following points:
- Number and types of animals
- Details of Procedures/Protocols
- Pain and Distress
- Monitoring
- Fate of the Animals

3.1 Number and types of animals
- Provide details relating to the number and types of animal relative to specific procedures. For example, include a breakdown of the number/type of animals per cohort, or the number/type of animals subjected to a particular procedure.
- Include any genetically modified animals and, where relevant, relate the phenotype/genotype to the procedures to be performed. For example, if only animals of a certain phenotype will undergo a particular procedure. Note that specific justification for the choice of type of animals should be addressed in Section 6.
- If the number of animals is unknown due to the nature of the work, for example, ecological field studies, provide a brief explanation of this.
- Provide, as relevant, details of the source of the animals and transport information, including details of acclimatisation post-transport.
3.2 Details of Procedures/Protocols
- Clearly outline what will be done to the animals.
- Outline the experimental or course design listing each protocol/procedure separately.
- Consider detailing how these protocols/procedures relate to the aims outlined in Section 2.2.
- Provide details of any procedures that will be used for genotyping purposes, e.g. ear-clipping.
- Provide a clear timeline of events, including the duration of each protocol/procedure, and the duration of breaks between protocol/procedure.
- Provide details of the maximum duration of each experiment, including holding time.
- Provide, as relevant, doses of all agents (e.g. drugs, analgesics, anaesthetics), delivery routes, blood collection volumes, etc. Use generic drug names rather than brand names where possible.
- Provide, as relevant, details pertinent to wildlife and agricultural research, e.g. capture, netting, trapping, handling, transport, marking/banding, and management of disease transfer.
- Provide details of the location/s where protocols/procedures will be performed.
- Where an Animal Care and Use Standard exists for procedures to be performed, the procedure can be described in the application with reference to the Standard, but must also include details specific to your project. Eg. "Using a clean 22 gauge metal gavage tube, mice will be administered substance x (at a dose rate of y mL/kg) once daily for seven days. The oral gavage procedure and post procedure monitoring will be conducted in accordance with the University’s Administration of Substances by Oral Gavage in Mice standard (Version 1)". Note that statements such as “Oral gavage will be performed as described in the Standard”, without project-specific details, are not acceptable.

3.3 Pain and Distress
- Provide an assessment of the potential adverse impacts on animal wellbeing for the duration of the project.
- Details of pain and distress should be included for each procedure, for both during and after performing the procedure. It should be noted that even minor and transient distress, such as that arising from handling, should be included.
- If using genetically modified animals, describe the impact of the genetic modification on the welfare of the animals.
- Consider the impact of issues such as captivity, isolation, environmental impoverishment, etc.
- Include, as relevant, an assessment of cumulative burden specific to repeated and/or sequential procedures, or if animals have been used previously in other projects.

3.4 Monitoring
- Explain how the wellbeing of animals will be monitored and assessed throughout the project. Monitoring should be specific to the type of procedure and the species/type of animal.
- If using genetically modified animals, describe how any welfare concerns associated with the genetic modification will be monitored and managed.
- Outline the frequency of monitoring and assessment, and provide details of who will be doing the monitoring, including after-hours monitoring and management of emergencies. Note that investigators are required to monitor animals separately and independently of checks performed by facility staff.
- Outline intervention criteria, and the actions to be taken if those criteria are reached.
- Outline the humane endpoints, i.e. the intervention criteria used to determine that an animal should be humanely killed, prior to the planned end of the experiment.
- Provide monitoring and intervention criteria sheets. For reference, sample monitoring and intervention criteria sheets are available here.
- When breeding new strains of mice, a mouse passport should be completed and submitted with the application.

3.5 Fate of the Animals
- Clearly outline what will happen to the animals at the end of the project.
- The planned endpoints of the work must occur as early as possible, so as to avoid and minimise pain or distress to the animals.
- Provide, as relevant, details of re-use and/or re-homing.
- Provide, as relevant, details of killing of animals.
4. INVESTIGATORS & COMPETENCY

In the table below, identify individual investigators against the protocols/procedures that they will be performing. For each protocol/procedure, indicate whether the investigator is ‘C’ (competent) or ‘T’ (needs training). Where an investigator is not performing a particular protocol/procedure, enter ‘N/A’ into the corresponding cell.

The Project Supervisor should determine an investigator’s competency or need for training for each protocol/procedure. When a researcher is competent in a procedure, a “C” should be placed in the relevant cell aligning the researcher with that procedure. For those investigators needing training, a “T” should be placed in the cell of the relevant procedure, and accurate training records must be kept. Investigators requiring training must not perform procedures without supervision until deemed competent. Note that where the person providing training is not involved in performing any other procedures within the project, they do not need to be listed as an Investigator. Where an investigator is not performing a particular protocol/procedure, enter “N/A” into the corresponding cell.

Note that competency is not transferable across species. Where multiple species are used within an application, training and competency details must be completed for each investigator and procedure specific to each species.

All Animal Facility Managers (AFMs) need to be named here if animals are to be located in University animal facility premises. Where the AFM is not performing any experimental procedures, they must still be named, and ‘N/A’ should be entered into the corresponding cells.

Animal facility staff, veterinary nurses, farmers or similar, must be listed here if they will be involved in performing procedures that are of an experimental nature and are outside of their day-to-day roles in monitoring, husbandry, etc. These must be people deemed competent by the Facility Manager, Project Supervisor or other competent assessor. Where procedures to be performed are the same for numerous personnel of the same classification, these investigators can be grouped as one entry.

Ensure all of the protocols/procedures outlined in Section 3, Experimental or Course Design, are listed in the table below. Where relevant, include monitoring as a procedure. If related, and where the details of competency and training are the same, multiple procedures may be grouped together (e.g. IV injection, IP injection, IM injections).

<table>
<thead>
<tr>
<th>Protocol/Procedure</th>
<th>IV, IP and IM injections</th>
<th>Behavioural Trials</th>
<th>Monitoring</th>
<th>Ear-clipping</th>
<th>After-hours monitoring</th>
<th>Management of emergencies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator 1</td>
<td>C</td>
<td>n/a</td>
<td>C</td>
<td>n/a</td>
<td>C</td>
<td>C</td>
</tr>
<tr>
<td>Investigator 2</td>
<td>T</td>
<td>C</td>
<td>n/a</td>
<td>C</td>
<td>T</td>
<td>T</td>
</tr>
<tr>
<td>Investigator 3</td>
<td>T</td>
<td>T</td>
<td>C</td>
<td>C</td>
<td>C</td>
<td>T</td>
</tr>
<tr>
<td>Animal Facility Staff</td>
<td>C</td>
<td>n/a</td>
<td>n/a</td>
<td>C</td>
<td>n/a</td>
<td>C</td>
</tr>
<tr>
<td>Animal Facility Manager</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>C</td>
</tr>
</tbody>
</table>

*Add/delete rows as necessary

5. HOUSING OF ANIMALS

5.1 For each species/strain requested, complete a row in the table.

If the conditions of housing are the same for all species, strains or classes of animals, simply enter ‘all animals’, or ‘all of class x’, in the below table.

<table>
<thead>
<tr>
<th>Species / Strain</th>
<th>Location</th>
<th>Housing</th>
<th>Grouping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mice - C57BL/6</td>
<td>Bio21 animal facility</td>
<td>Standard</td>
<td>Grouped</td>
</tr>
<tr>
<td>Cattle - Jersey</td>
<td>Vet Science Werribee cattle facilities</td>
<td>Standard</td>
<td>Grouped</td>
</tr>
</tbody>
</table>
5.2 If relevant, provide further details of housing, including, as relevant, details of outdoor housing, any special housing requirements, details of enrichment etc. Where housing is not applicable, please explain why.

Failure to provide appropriate housing has clear impacts on the wellbeing of animals and potentially on research quality. Provide details such that the AEC can be assured that the housing is appropriate and meets relevant guidelines or other requirements.

Include, as relevant, details of:
- Outdoor housing;
- Group housing of animals;
- Special housing requirements;
- Environmental enrichment;
- Justification for individual housing.

6. REPLACEMENT

Replacement refers to methods that avoid or replace the use of animals. Examples of replacement include the use of:
- Animal cell lines, tissues and cells;
- Human volunteers, tissues and cells;
- Mathematical or computer models;
- Less sentient animals, e.g. invertebrates such as Drosophila.

6.1 Explain why it is necessary to use animals for the proposed work.

The unjustified use of animals is not ethical. State reasons why animals are necessary for the project.

6.2 Provide evidence for the consideration of alternatives to animal use.

Applicants are required to consider the principle of replacement where possible. List possible alternatives to animal use and state why these are unsuitable. For example, evidence from the literature may indicate that scientifically valid outcomes can only be achieved using your chosen animal model.

6.3 Provide justification for the choice of animal/s.

Provide justification for the animals chosen, including species, strain, genetic modification, sex and age of animals.

7. REDUCTION

Reduction refers to methods that minimise the number of animals required to achieve the aims of the work. Applicants must demonstrate that the minimum number of animals required to attain scientifically meaningful or statistically significant results will be used. Reducing the number of animals used should not result in greater harm, including pain and distress, to the animals that are used.

7.1 Provide statistical or other justification relevant to the project for the number of animals requested. Break down the total number by procedures, treatments, repeats, groups, etc.

- Justify animal numbers with reference to the experiments to be performed. Where relevant, include statistical considerations such as calculations for sample size and power analyses.
- Animal numbers and calculations should be presented clearly and logically.
- Include tables as necessary.
- For teaching projects, information should be provided relative to the ratio of students to animals, and the number of times each animal will be used per class, and/or day, and/or week.
- Note that the use of too few animals may invalidate results and result in wastage of animals.
- If the number of animals is unknown due to the nature of the work, for example, ecological field studies, provide a brief explanation of this.

7.2 Have the animals been used in another project? If so, outline the cumulative burden and provide justification for re-use.

- The number of animals used may be reduced by appropriate re-use of animals; however, animals used in previous research or teaching activities may experience added distress or pain. The effect/s of cumulative procedures on animal wellbeing should be described, and their use in this project should be justified. Include, as relevant, ID numbers of previous projects.
- As an additional consideration to reduce animal use, describe if the animals or their tissues can or will be used in another project upon completion of the proposed work.
8. **REFINEMENT**

How have techniques been refined to minimise impacts on animal welfare?

Refinement refers to methods that minimise pain and suffering and improve animal welfare for those animals that are used. Describe, as relevant, how protocols/procedures, housing and husbandry have been refined in order to minimise the impact on animals. In addition, describe strategies that will be implemented to support and safeguard animal welfare, and how these will be reviewed during the lifetime of the activities.

9. **OVERALL JUSTIFICATION**

Explain how the potential impacts on the wellbeing of animals in this project are justified by the potential benefits of the proposed work.

A scientific activity that uses animals is considered ethical under the definition of The Code where the potential benefits of the work outweigh the potential impacts on the animals, and steps have been taken to minimise those impacts.

Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes. This respect is demonstrated by:

(i) Using animals only when it is justified
(ii) Supporting the wellbeing of the animals involved
(iii) Avoiding or minimising harm, including pain and distress, to those animals
(iv) Applying high standards of scientific integrity
(v) Applying Replacement, Reduction and Refinement (the 3Rs) at all stages of animal care and use:
   (a) The Replacement of animals with other methods
   (b) The Reduction in the number of animals used
   (c) The Refinement of techniques used to minimise the adverse impact on animals
(vi) Knowing and accepting one’s responsibilities.

A judgment as to whether the proposed use of animals is ethically acceptable must be based on information that demonstrates the principles above, and must balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits of the work.

10. **GLOSSARY**

Provide descriptions/definitions of abbreviations and scientific terms in language that can easily be understood by the lay reader.