AMENDMENT REQUEST GUIDANCE DOCUMENT

This Animal Ethics Amendment Request 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.

WHAT IS AN AMENDMENT?

An amendment is a minor change to an approved project that remains within the same aims of the original project, and does not significantly change, or reduces, the impact on animal welfare. This may include:

- Request to add or remove staff or students
- A request for additional animals, but not so many as to make the AEC question the integrity of your research design or aims of your project
- An extension to the duration of the project, for example, due to leave or issues with animal availability
- Minor amendment to, or addition of, a procedure or protocol

An amendment that falls outside of these guidelines, or increases the impact on animal welfare, should be submitted as a new application.

HOW TO USE THE AMENDMENT REQUEST GUIDANCE DOCUMENT

1. This document is designed to be opened at the same time as completing your Amendment Request 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 Amendment form.
3. Click on the Section Number you require guidance for and you will be directed the relevant section of this guidance document.

Example of Section 2.3 of Amendment Request Guidance Document
WHAT TO DO WHEN YOU HAVE COMPLETED YOUR AMENDMENT REQUEST

1. It is highly recommended that you have your amendment pre-reviewed by a trusted colleague experienced in preparing animal ethics applications prior to submission.

2. Save your amendment as a Microsoft Word file (not a PDF) using the new version ID number generated by Themis as the file name.

3. Upload your amendment into Themis as attachment type “Application”.

4. Upload any new or amended Monitoring and Intervention sheets as attachment type “Monitoring and intervention proforma”. Upload any other new or amended attachments as attachment type ‘Miscellaneous’. Any existing documentation that is still relevant to the project as a whole, including unchanged Monitoring and Intervention sheets, should also be uploaded. Ensure all attachments are named clearly and logically.

RESPONSIBILITY OF THE APPLICANT

1. Researchers 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 Amendment Request, 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 Amendment Request 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 Amendment Requests.

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 Project ID and Title:

Ethics ID No:  {Provide the new version number assigned by Themis when the amendment application was created.}

Project title:  {Include the exact title as given in the preceding version.}

2. AMENDMENT DETAILS

2.1 Request to add or remove Investigators

☐ Yes – these changes will also need to be made in Themis  ☐ No – Go to Section 2.2

When adding new investigators, list each protocol/procedure that they will be performing and indicate whether the investigator is ‘C’ (competent) or ‘T’ (needs training). Enter ‘N/A’ when an investigator is not performing a particular procedure. For instructions on changing procedures for investigators, and for including Animal Facility Managers, animal facility staff, veterinary nurses, farmers, etc., refer to the ‘ANIMAL ETHICS AMENDMENT GUIDANCE’ document. Note that investigators requiring training must not perform procedures without supervision until deemed competent.

*Note that when adding or removing Investigators to/from a project, these changes will also need to be made in the ‘Personnel’ section (Step 3) in Themis.*

2.1.1 Adding New Investigators

In the Investigator competency table, list each protocol/procedure described in the application and indicate whether the new Investigator is ‘C’ (competent) or ‘T’ (needs training). The Project Supervisor should determine an investigator’s competency or need for training for each protocol/procedure. For those investigators needing training, **accurate training records must be kept locally. 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 any new procedures that form part of this amendment (Section 2.4) are included in the Investigator table.

2.1.2 Removing Investigators

When an Investigator will no longer be involved in a project and is to be removed from the Investigator list entirely, this can be requested in the space provided below the Investigator table on the Amendment Request form. When removing an Investigator/s, ensure that the responsibility for procedures previously performed by this Investigator/s now lies with an alternate Investigator/s. Note that this may require updating the procedures/protocols for other Investigators on the project (see Section 2.1.3 below).

If changes include removing an Investigator from some of the procedures within the project, but not from the project as a whole, enter ‘remove’ in the cell/s associated with the procedure/s that this Investigator will no longer be performing. Again, the responsibility for these procedures should now lie with an alternate Investigator/s.
2.1.3 Adding or updating procedures for existing Investigators
Where an additional procedure/s is to be performed by an existing Investigator/s on the project, enter a sub-heading “Procedures update only” in the Investigator table, enter the Investigator/s name below the sub-heading, complete the Competency/Training classification for all procedures this Investigator/s will be performing, and highlight the new/updated procedures. An example is shown below, where Investigator 1 is an existing Investigator on the project who has previously been listed as competent (C) in injections and monitoring, and whose procedures are now being updated to include behavioural trials and ear-clipping, in which they still require training (T). In this example, Investigator 4 is new to the project, and Investigator 3 is being removed from the project.

<table>
<thead>
<tr>
<th>PROTOCOL/PROCEDURE</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV, IP and IM injections</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INVESTIGATOR</th>
<th>IV, IP and IM injections</th>
<th>Behavioural Trials</th>
<th>Monitoring</th>
<th>Ear-clipping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator 1</td>
<td>C</td>
<td>T</td>
<td>C</td>
<td>T</td>
</tr>
<tr>
<td>Investigator 4</td>
<td>C</td>
<td>T</td>
<td>T</td>
<td>n/a</td>
</tr>
</tbody>
</table>

{Provide any further relevant information regarding changes to investigators here.}

Example: Investigator 3 has left the University and therefore needs to be removed from this application. The responsibility for procedures previously performed by Investigator 3 will now be performed by Investigator 4.

2.2 Request for time extension

☐ Yes  ☐ No – Go to Section 2.3

Proposed new end date: {new date}

An extension of time may be requested if, due to unforeseen circumstances, the project has not been able to be completed within the initial period of approval. Such instances may include staff absence due to maternity leave or illness, and animal or equipment unavailability. You should enter the proposed new end date to the project, ensuring you have accurately calculated this from the current end date listed in Themis. In Section 2.5 below you should be clear about the amount of additional time being requested, and provide full justification for why this is needed.

It should be noted that approval to extend a project beyond 31 December in a calendar year will require the provision of additional Annual Reports and Animal Use Returns, in line with the annual reporting requirements of the University and the Department of Economic Development, Jobs, Transport and Resources (formerly the Bureau of Animal Welfare).

2.3 Request for additional animals

☐ Yes – these changes will also need to be made in Themis  ☐ No – Go to Section 2.4

<table>
<thead>
<tr>
<th>Species/Strain/Sex/Age</th>
<th>No. Requested in this amendment</th>
<th>New Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Provide details of:
- The source of the animals, any transport information and housing details; and
- Statistical or other justification relevant to your experiments for the numbers requested.
Note that when requesting additional animals, the changes will also need to be made in the ‘Animals Requested’ section (Step 2) in Themis.

Provide, as relevant, details of source of the animals and transport information, including details of acclimatisation post-transport, as well as housing information.

It is also necessary to provide statistical or other justification relevant to your experiments for the number of animals requested.

- Justify animal numbers with reference to the experiments to be performed, including procedures, treatments, repeats, groups, etc. 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.

2.4 Request to amend or add procedure/s

☐ Yes  ☐ No – Go to Section 2.5

Describe the procedure/s in full, including the impact of the procedure/s on the animals and steps that will be taken to minimise this impact.

This section should clearly describe the proposed changes to procedures, or additional procedures to be performed, including the impact of the procedure/s on the animals and steps that will be taken to minimise this impact. This information should be clear and concise, but must contain enough detail that a proper assessment of the impacts of the procedures on each animal (or group of animals) can be made.

Similarly to when preparing a new application, the following points should be covered:

- Details of Procedures/Protocols – outline what will be done to the animals;
- Pain and Distress – assess the potential adverse impacts on animal wellbeing for the duration of the project;
- Cumulative Burden – where relevant, give an assessment of the cumulative burden resulting from new procedures being conducted in addition to existing (previously approved) procedures;
- Monitoring – explain how the wellbeing of animals will be monitored and assessed throughout the project; and
- Fate of the Animals – outline what will happen to the animals at the end of the project.

2.5 Justify the requested amendment

Justify in full why this amendment is needed, including an explanation of how the potential impacts on the wellbeing of animals in this project are justified by the potential benefits of the proposed work.

You should:

- Provide a clear justification for the purpose of the amendment;
- Include the relationship to the aims and design of the original project, and any previously approved amendments; and
- Detail how the principles of the 3R’s – Replacement, Reduction and Refinement – have been met.

This section should be written in plain English and be clear and concise.