Australian National University

ANIMAL ETHICS APPLICATION TIPS

BIOMEDICAL

Top 10 tips

1. Write your application in plain English.
2. Ensure that the application clearly outlines the 'lifetime' experience of the animals in the protocol. The Committee members need to be able to understand the various procedures/experiences that an animal will be exposed to and the frequency/duration/rest periods/transport etc associated with that timeline. Diagrams and flow charts can help with this.
3. Justify the number of animals requested – seek help from the ANU Statistical Support Network to determine the appropriate statistical methods for your research.
4. Be honest and clear in the impact assessment. Each procedure/event in the animal's life will create some impact – spell this out and clearly outline how you will minimise these impacts.
5. Make sure each team member has their profile up to date with their competencies added.
6. Liaise with the ANU Vet Services Team and Animal Ethics Team in advance of your application. They can provide you with advice on the application process and specific veterinary advice on anaesthetic protocols, drug doses, monitoring sheets, and more.
7. Outline the monitoring for different stages of the animal's lifetime. Provide specific score sheets for activities that are likely to cause pain or distress to your experimental animals.
8. Check the AEC published standards, guidelines and templates for information on common procedures performed at ANU. You can refer to these standards and do not need to repeat all the details in the application as long as you follow the standards as they are written.
9. Remember to save your animal ethics application regularly!
10. Ask us! Contact the Animal Ethics Team at animal.ethics@anu.edu.au or the Vet Services Team at vetservices.ris@anu.edu.au.

Beginning your application

Prepare

- Animal Ethics Applications are submitted through the Research Ethics Management System (REMS).
- Log into REMS by entering your ANU credentials and set up your profile.
- If you are a team leader and wants to establish a research team, please contact the Animal Ethics Office - animal.ethics@anu.edu.au. Once your team has been created, please add your team members and assign a role within your team.
- Next add the team members to your projects. Animal ethics protocols are now referred to as a Projects in REMS. Assign a specific role for each member within the project.
- Ensure that all members of your team have completed the compulsory animal ethics training. Further information can be found here.
- Visit the REMS SharePoint for Animal Ethics training videos, user guides and FAQs.
- Consider how you will organise your program of experimental work into 'Animals', 'Activities' and, 'Procedures'.
- Add research group specific procedures to your team which, can be added/linked to your animal ethics application form.

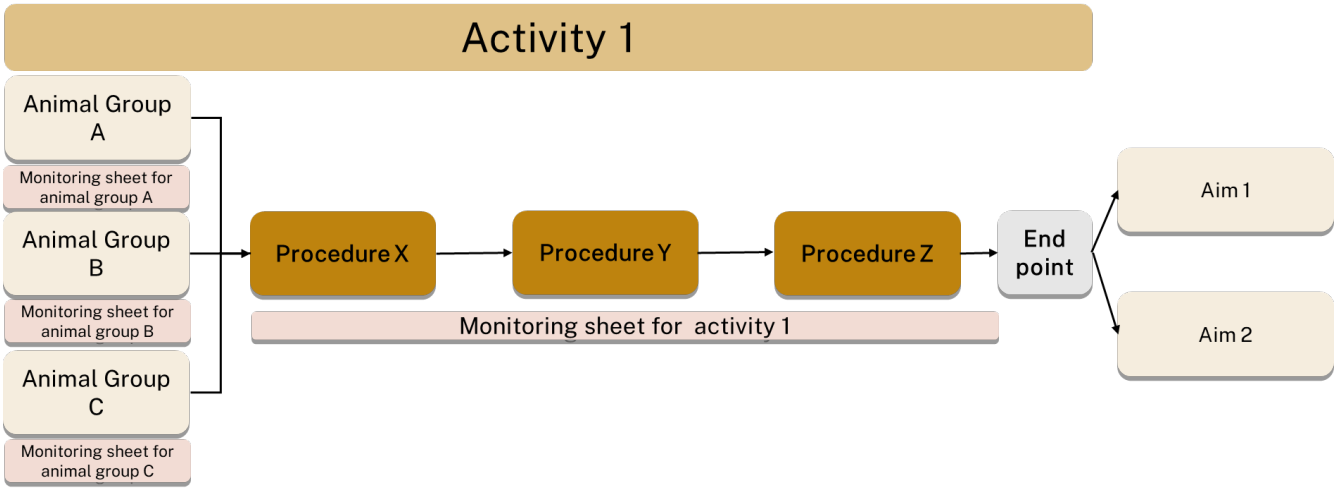

Figure 1. A diagrammatic representation of an example Activity 1, containing 3 procedures, performed on 3 different animal groups. This activity also include 3 monitoring sheets. The data collected from this Activity will help address Aims 1 and 2 in the Animal Ethics Project.

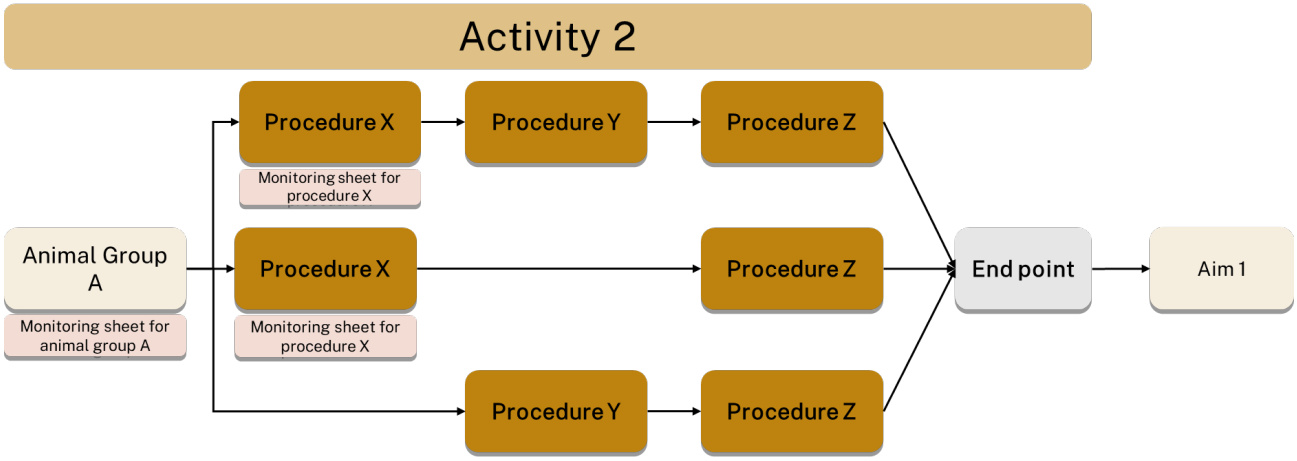

Figure 2. A diagrammatic representation of an example Activity 2, containing 3 procedures, using one animal group. This activity also contains 2 monitoring sheets. While the number and order of procedures differ between some animals, all data generated is addressing aim 1 of the Animal Ethics Project.

Check the Animal Ethics Submission Dates

The dates of the submission deadlines and Animal Ethics Committee meeting can be found on the ANU website.

We strongly recommend that you prepare your application early to allow sufficient time for review and feedback prior to submission. Ensure that your proposed start date is after the meeting date that you have submitted to. It may take several weeks for approvals to be processed post meeting especially if the AEC has post meeting questions/requests, therefore, this should be factored in when choosing the start date.

If you have a project that is due for renewal, we recommend submitting your renewal application at least two AEC meetings prior to your end date.

It is best to request the maximum duration of 3 years, as there is no penalty for finishing your project early but extensions are only possible for a maximum of 3 months.

Also please note that amendments cannot be submitted for applications during the 3-month extension period.

Completing your Application

Important: use the Save form button to save updates regularly since the form does not auto-save.

This document contains some useful information for selected sections of the Biomedical Animals Ethics Application Form based on previous researcher questions. If your question is not answered by this guide, please contact the animal ethics team at animal.ethics@anu.edu.au

Administrative Details

1.2 Aim(s)/Objective of the project

The purpose of this question is to give the Committee a broad overview of the purpose of the project, and also meets the reporting requirements for some states.

The definitions of each category, including examples, can be found at the end of this document in Appendix 1.

1.3, 1.4 Proposed start and finish date

See further information above in 'Prepare' section.

Investigators

3.2 Role and responsibilities on the protocol

The purpose of this question is to detail to the Committee who will be working on the project, their level of responsibility and their experience.

Top Tips

- Ensure a member is allocated the role of 'nominee'. This member will be the back-up contact for the project should the PI be unavailable and should therefore have a good understanding of the project (e.g. nominee may be a supervisor, colleague, senior research student or lab manager).
- If a student is listed in the project, please indicate the student type ie. PhD, Masters, Honours etc.
- Ensure you detail all the following information for each person:
    - A brief introduction, eg. the persons role at the University, research group, any relevant previous Animal Ethics Applications that the person was named on.
    - Their general experience with the species/type of program
    - Their specific experience with each procedure to be undertaken under the project or clearly define where they will not be responsible for undertaking a procedure.
- Where individuals are not yet trained on a procedure this should be clearly outlined with detail on the proposed training for them to meet competency for the required procedures.
- If a procedure is added/linked to a project, all the members listed under the procedure must provide their competency (include providing any relevant certificates).

Common Issues

- Principal investigators and Nominees must be ANU personnel.
- Lack of information provided on specific Procedure, in particular the advanced techniques referred to in the project.

Project Description

5.1 Project design

The purpose of this question is to ensure that all members of the Committee can understand a general description of the proposed research and why the research is being planned. The Committee is made up of a combination of individuals with different

backgrounds; vets, scientists, animal technicians, welfare representatives and lay people representing the general public.

It is important that all the members of the Committee have a good understanding of the intention of your project, the type of research and the impact on the animals. Even though this question specifically asks for a description in plain English, keep this in mind throughout the entire application process and ensure that you define acronyms and complex ideas to assist the non-science members of the Committee.

Top Tips

- Keep this to the maximum 500 words.
- Ensure it is truly a lay description – aim your description to an adult without a science background.
- Set out clear aims/objectives/hypothesis for your work.
- If this is a renewal of a previous project, make it clear how your work has progressed to this project.
- If the work is novel and you are unsure of the outcome or impact on animals, you may want to consider a pilot study.

Common problems

- Language is too scientific and needs to be in plain English.
- The information is about the disease they are investigating rather than their research specifically.
- Clear objectives and hypothesis not provided.
- The growth of a project between historically approved projects is not clear and there is no argument for progression of research.

5.2 Potential benefits

The purpose of this question is to outline the expected benefits or results from the project and provide information for the Committee to address the harm/benefit analysis that is integral to the Committee's review of the application.

You should use this opportunity to clearly state the expected benefits from the project. These benefits should demonstrate scientific or educational merit and potential benefits to humans, animals or the environment.

Top Tips

- The higher the potential impact on the animals, the greater the benefit which must be demonstrated.

Common Problems

- The impact and mitigation steps are often repeated rather than justifying the benefit of the work over the impact to the animal which the Committee is required to assess (Code section 1.3).

5.3 Replacement and essential use of animals

The purpose of this question is to allow researchers to directly address the "Replacement" component of the 3Rs.

In this section you are asked to provide details of why the use of animals is essential to achieve the stated aims, including the possible alternatives available, and if alternatives are available, why these alternatives are not suitable.

Top Tips

- Simply stating that animal use is the way it has always been done is not acceptable – you need to justify why this particular work must be done on animals and there why there are no alternatives.
- If there are non-animal alternatives, you need to justify why you are not using these (or if you can use them – perhaps outline a pilot study where you can run side by side for verification).
- This shouldn't just discuss alternatives for the main aim of the project but also for smaller parts (ie can in vitro work be used to help define which drugs will be used etc).
- Further information on alternatives to animal research can be found on the ANU animal ethics resources, training and support website.

Common Problems

- No acknowledgement of any of the possible alternative options.
- No justification of why named alternative options are not appropriate to achieve the stated aims.

5.4 Reduction

The purpose of this question is for researchers to justify the number of animals required for an animal ethics protocol. Please detail the relevant aspects of the experimental design including the statistical considerations (including power calculations) to justify animal numbers requested.

Top Tips

- It is strongly recommended that you seek advice from the ANU Statistical Support Network, or seek other statistical support for determination of appropriate statistical methods for your research. Further information can be found on the animal ethics website.
- To justify animal numbers required, explain the outcomes being measured, the characteristics of the data being collected and the parameters used in power calculations.
- Please request an appropriate number of animals (based on good statistical design). The use of too few animals may invalidate the experimental result and result in the wastage of animals. The Committee would rather more animals are utilised for good quality data and outcomes, than too few animals with no appropriate analysis able to be completed which means they would be wasted.
- Do not state the animal group numbers are 'based on previous experience' – this does not justify the numbers sufficiently. Where appropriate please provide details of the methods/calculation(s) that were used to determine the number of animals and the statistical validity of the proposal.
- If breeding – please include a breakdown of the numbers, differentiating between the breeding and experimental numbers, and how the number of animals bred relates to the number required for the experimental work.

NOTE: REMS includes a set of questions on breeding in section 6 where breeding numbers can be noted.

- Where you have a number of experiments it is useful for the Committee to receive a table explaining the numbers to be used. The rich text boxes used in the REMS system allow for tables to be directly entered, or files containing spreadsheets of diagrams can be uploaded.
- If a large number of animals are being requested due to an unpredictable experimental course, a decision tree or flow chart defining how you will decide which experiments will go ahead and which will not can be very helpful.

Common Issues

- Lack of description of statistical design.
- Very large numbers of animals requested without any clear justification or reasoning, or historical reasoning only (e.g. 'we have always used X number of animals for this experiment').

5.5 Refinement

The purpose of this question is to allow you to address the "Refinement" part of the 3Rs. In order to address this question, please briefly outline the welfare impacts of the activities being performed on the animals being used. Then outline how refinements can be used to reduce the impact of these activities.

Refinement refers to any action or method that minimises the pain, suffering, distress or harm that may be experienced by animals during research, and which improve their welfare. Refinement applies to all stages of animal usage from breeding and routine care to experimental procedures. Examples of refinement include ensuring the animals are provided with housing that allows the expression of species-specific behaviours, using appropriate anaesthesia and analgesia to minimise pain, and training animals to cooperate with procedures to minimise any distress.

Common refinements used at ANU include: training of individuals to perform procedures competently, the use of monitoring sheets (templates available here), the provision of analgesia or use of anaesthesia for invasive procedures, group housing where possible, and voluntary oral administration of medications.

Top Tips

- Monitoring or score sheets are required to be uploaded for Q11.1 as part of the section 'Other Details'.
- Templates for monitoring sheets (also called score systems) can be found here.
- The Vet Services Team can help develop refinements and monitoring sheets for your project, contact: vetservices.ris@anu.edu.au
- You should aim to address all of the impacts you identified and how these will be minimised.
- Ensure that any changes you have implemented in previous projects that have improved the welfare of the animals is detailed in this section. This may include outcomes of UAE investigations or your own applied improvements.

Common Problems

- No monitoring sheets/score systems are used.

- The welfare impacts of procedures are minimised without justification.

5.6 Activities that severely compromise animal welfare

The purpose of this question is to identify projects that include procedures or activities that cause a severe compromise to animal wellbeing, where the 3Rs (Replacement, Reduction and Refinement) cannot be fully applied.

See Appendix 2 for examples of each category.

Please contact ANU Vet Services Team if you think your project will include any of the following activities: prolonged restraint or confinement, reuse and repeated use of animals, unrelieved pain and distress including where the planned endpoints will allow severe adverse effects.

5.7 Categories of experimental interventions

The purpose of this question is to give the Committee a broad overview of the interventions being performed on the project, and also meets the reporting requirements for some states.

The definitions of each category, including examples, can be found at the end of this document in Appendix 3.

Please note that in this instance 'Production of genetically modified animals' does not include the breeding of established GM lines of mice (or their crosses) for experimental use. Please also see the definition of 'Death as an endpoint' and contact ANU Vet Services Team if you believe your research will fall into this category.

5.8 Will any types of animals be excluded from experimental activities?

5.8.1 Please provide details on the exclusion criteria and justification for the exclusion of these animals *

The purpose of this question is to provide The Committee with information on what animals are not being used, and which, therefore, may be considered 'wasted'. For example, males may not be used, or animals with specific genotypes.

If excluding certain types of animals from your research, please provide an expected percentage of animals that will be excluded.

Please also provide a justification for the exclusion of these animals, and what can be done to minimise the number of excluded animals (for example, by changing a breeding system to generate different percentages of genotypes).

Animals

6.1 Add animal group

How should I define animal groups?

You can add animal strains/phenotypes/lines individually, or where individual strains/lines share similar characteristics, husbandry conditions and procedures being performed, you may choose to enter multiple strains/lines as one animal group.

Please consider grouping strains/phenotypes/lines with respect to: immune status, animal care needs, other welfare issues such as tumour development, or development of neurological disease.

6.3 Has the phenotype been fully characterised (in regards to the wellbeing of the animal group)?

The purpose of this question is to assess the likelihood of unknown negative welfare outcomes occurring for a strain. Fully characterised, in this instance, refers to having sufficient information available to assess the likely welfare impacts that will occur for this strain. Ideally a phenotype report will be provided which includes: description of the strain, source of the strain, genetic alteration (if any), affected organs or tissue, impact on breeding and lifespan, known abnormalities (including incidence or prevalence) and their impacts on welfare and expected mortality rate.

The information required for this section relates to the 'baseline' phenotypes of animals, ie. the state of animals without experimental intervention. This section does not include possible interactions between phenotypes and procedures/treatments. To address the possibility of phenotype interactions with interventions, please see section Activities: question 8.5 Cumulative impacts of activities and procedures.

6.4. 6.5 and 6.6 List of strains

The strains/mouse lines used in the animal ethics project must be included in the response to one of these questions. Strain information can be provided in the following ways:

- Mice and rat strains can be selected from the Rodentity drop down list, AND/OR
- As a typed, plain text list, AND/OR
- Uploaded in the form of a PDF, word or excel spreadsheet (recommended where large numbers of strains are to be used)

New strains/mouse lines can be added by using the plain text option or uploaded a document containing the proposed strains to be used. If you would like to enter new strains using the Rodentity drop down list you can ask for the mouse line to be added to Rodentity ahead of time by contacting APF animal operations: animal.ops.apf@anu.edu.au

6.10 Total number required

This field cannot be edited and is automatically calculated once the animal numbers are added to the specific animal group in the 'Activities' section.

6.11 Describe the reason for choosing this animal

The purpose of this question is to provide The Committee with information on how the animals used allow the experimental aims of the activities to be addressed. This may relate to the species being used, the characteristics of the strain, the genetic characteristics of the animals, or the sex of the animals.

Total animal number

Total animal number will appear automatically once animal numbers are added to each animal group to the relevant activity in the 'Activities' section. If the number has not been updated, please save the form and the numbers will then be updated.

Activities

An activity includes all procedures that occur to an animal and that address an experimental aim or part of an experimental aim. See Figure 1 above.

8.2 Describe the experimental design

The purpose of this question is to explain to the Committee a step-by-step description of what will happen to each animal (or group of animals) in chronological order. This allows the Committee to assess the likely cumulative impact of the activity on the animal or animal group. This also includes the fate of the animal at the conclusion of the activity.

Top tips

- Ensure that you clearly outline the 'lifetime' experience of the animals in each group. This includes procurement of the animals, transport to or between facilities, and acclimatisation periods.
- Include blood volumes for each blood collection instance and/or volumes of substances administered.
- Diagrams showing activity timelines are strongly encouraged and can be included in the rich text box or uploaded as a separate file (pdf, power-point, word doc etc)
- Breeding of animals for experimental use is considered an Activity

Common Issues

- Unclear time lines that make it difficult to follow an animal or animal group through the activity from start to finish.

8.5 Cumulative impacts of activities and procedures

The purpose of this question is to address the specific welfare impacts that the activity will have on the animals or animal groups undergoing the activity.

As part of addressing this question, please comment on the impact of the activity including: the number of different interventions/procedures performed, the frequency of these interventions/procedures, including cumulative impacts of blood loss or tissue changes associated with repeated injections, and the expected adverse welfare outcomes (eg. weight loss, pain, changes in mobility, mortality).

Then, based on the welfare impacts identified, what will be done to minimise these impacts? There may be some overlap with your response to Q 5.5 Refinements, and responses may include increased training, provision of analgesia, use of anaesthesia, increased monitoring frequency, and the addition of specific monitoring parameters and humane endpoints.

This question can also be used to outline any possible or expected interactions between the phenotypes within the animal group and the activity (including expected adverse events and mortality rates).

Top tips

- Ensure that you clearly outline the 'lifetime' experience of the animals in each group. This timeline of an animals use can be very helpful for the Committee to understand the cumulative impact on the animal. A timeline can be attached as a separate document in this section.
- A 'lifetime' timeline includes procurement of the animals, transport to or between facilities and acclimatisation periods. You should aim to address all of the impacts you identified during the animal's 'lifetime' and how these will be minimised.
- Include a description of expected adverse events for the activity including how these will be identified (ie. monitoring systems), and a mortality rate if interventions are likely to be high impact.
- Ensure that any changes you have implemented in previous project that have improved the welfare of the animals is detailed in this section. This may include outcomes of UAE investigations or your own applied improvements.

Common issues

- Timelines are incomplete and some procedures are not added.
- The welfare impacts of some procedures are minimised or not clear and therefore not addressed appropriately.

Procedures

Select procedures

The purpose of this question is to allow the Committee to understand what specific procedures will be undertaken and how. Researchers are asked to add the procedures referenced in the activities.

PR01 If there is a variation to the procedure, please describe

This section allows researchers to detail any variations from the Procedure selected. Examples of variations include: different needle size, change in volume administered, change in frequency of procedure, if lab members or trained Animal Care technicians would be completing task etc.

Procedures uploaded by researchers

If the procedure you need is missing you will need to add it to your team's procedure list under the Team -> Procedures left hand menu option.

Procedures uploaded by researchers will only be accessible to members of the 'team'. Other research groups will not be able to access these procedures. For procedures with assessable skills, a training and competency framework will be required as part of the procedure.

Global procedures
Some common procedures will be available in the Global list for researchers to add to their protocols. 'Select Procedures' and a list of all the global list of procedures will appear to chose from.

Procedure approval process
Procedures must be submitted separately to an Animal Ethics Application from. However, both can be submitted concurrently and, the procedures will be assessed at the same time as your animal ethics application. When the procedures are approved, they are used as part of the approved Animal Ethics Protocol.

Top Tips

- If ANU Animal Ethics Committee Guidelines or Standards are available, it is useful to refer to these.
- If you need to adjust how something is performed compared with these AEC approved guidelines, then this must be made clear in your project application (you can add this information to PR01 Procedure Variation).
- Do include humane killing in the procedure section. If several methods are listed, ensure it is clear which method will be used in each setting.

Common Issues

- Vague responses without details on the steps taken within a procedure.
- Lack of detail leads to many further questions being asked in the Q&A process and leads to unnecessary delays in approval.
- Procedures not updated from previous projects when improvements may have been made by the group or under veterinary advice, or best practice standards have changed (e.g. anaesthesia drug doses, methodology).

Agents
The purpose of this question is to ensure all compounds being provided to animals are listed in the project and that drug doses are accurate and suitable for the procedures being undertaken. Agents detailed in the Procedures section or in SOPs must still be included in the Agents section.

Further information on the use of drugs in research animals can be found on the animal ethics website.

10.3 Adverse or side effects
Please list any expected side effects from the agent being administered or if it is a novel compound, provide any information of the action and side effects of any similar agents.

10.4 Dose rate
Please provide agent dose rates in the form of mg/kg (or similar), not the volume being administered or the total dose per mouse.

10.10 Is the agent a non-pharmaceutical grade compound?

See Document 10: ANU Position Paper – Use of Non-Pharmaceutical Grade Discovery Compounds in Animals V2.0 for full details.

Briefly, a non-pharmaceutical compound is a drug or medication that is not manufactured to a chemical purity standard that is recognized by official groups such as the United States Pharmacopeia-National Formulary (USP/NF) or British Pharmacopeia (BP) or similar. This includes novel or 'discovery' compounds that have not previously been used in animals, or drugs that are currently under development and not yet available in a pharmaceutical grade preparation.

If you are using a non-pharmaceutical grade compound please address the criteria listed in the AEC Approved Position Paper.

Top Tips

- Ensure your drug doses are accurate and within best practice guidelines.
- Consult with the Vet Services Team where you are unsure on appropriate drugs or doses for your procedure.
- Include the % of any inhalational anaesthetics and the flow rate for oxygen/gas to be provided simultaneously.
- Refer to or attach a specific procedure where relevant.

Common Issues

- Lack of information and detail provided for dose rate and expected side effects
- Trade name only given (need to give the name of the active ingredient)

Other Details

11.1 Please upload any relevant monitoring sheets

The purpose of this question is to detail to the Committee how animals will be monitored throughout their lifetime. This includes monitoring prior to, during and after activities are conducted. Depending on the activity, animals may require multiple monitoring sheets during their lifetime.

Top Tips

- Utilise the AEC approved Mouse Score System where appropriate.https://services.anu.edu.au/research-support/ethics-integrity/animal-ethics-policies-guidelines-and-forms)
- Seek advice from the Vet Services Team to customise monitoring sheets to your activities.
- For surgical procedures or during the use of anaesthetics animals must be monitored with an anaesthetic monitoring sheet. Please see the AEC approved Document 008: Surgery and Anaesthesia Monitoring Guidance V2.0 template https://services.anu.edu.au/research-support/ethics-integrity/animal-ethics-policies-guidelines-and-forms)
- Include information on the monitoring sheet regarding intervention or humane end points, as well as responsibility for checks (researcher vs animal technicians)

Common Issues

- No monitoring sheets used during anaesthesia.

- Poorly designed score cards that do not have clear intervention points or humane end-points detailed.
- Monitoring sheets not available in-room.
- Poor communication between researchers, students and animal technicians leading to checks being missed, or monitoring sheets not being used properly.

11.4 Are there hazards to animals and/or humans?

The purpose of this question is to ensure that risks to staff and researchers, including animal care staff, vets and other members of staff, are aware of the risks of the project, that adequate risk assessment has taken place and protective measures have been identified for implementation.

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Top Tips

- Consider all chemical agents used in experiments, and the potential exposure to research and animal care staff.
- If using isoflurane consider the risk of exposure to waste anaesthetic gases.
- If using cytotoxic compounds ensure you engage with the animal care team and follow required local procedures.
- Complete a risk assessment for all work to be undertaken.
- Summarise what measures have been and/or will be put in place to mitigate/minimise risks.

Common Issues

- Underestimating or underreporting risks.

Animal housing, husbandry and care

13.3 How will animals be housed?

The purpose of this question is to provide information to the Committee on the husbandry of animals being used for research as it relates to 'supporting the wellbeing of animals'.

If animals are not housed in an ANU managed facility, please provide details on the housing of animals including types of cages used, size of the cages, density of animals, bedding used, environmental enrichment provided and any other relevant details.

For mice and rats being held in HEB or JCSMR in APF managed facilities the standard conditions can be found in Appendix 4. Please add any relevant details specific to your project to this general description.

13.6 Provide details of care

For mice and rats being held in HEB or JCSMR in APF managed facilities the standard conditions can be found in Appendix 4. Please add any relevant details specific to your project to this general description.

Documents, such as a husbandry handbook, can be uploaded to the rich text boxes to address this question.

Top Tips

- See Appendix 4 for general housing details for animals held at HEB and JCSMR under the APF.
- Ensure that experimental areas are included as well as areas where breeding and long term holding is undertaken.

Common Issues

- Copy and paste from old projects is used without updating relevant information from the day to day management of animals.

13.9 Transport – Will the animals be transported to another location during the course of the project?

And 13.9.1 Provide the location details and how they will be transported.

Please include information on the movement of live animals (in line with hierarchy requirements) between rooms and facilities, as well as how animals will be moved. The AEC approved Document 002: Guidelines for Animal Transport V2.0 can be found on the animal ethics website.

Completing your application

Generating a copy of your application

Your application can be accessed on the REMS system throughout the application process. A PDF copy can be generated at any time while the Project is in the 'view' mode.

Signatures

The PI, Nominee and all investigators must complete declaration upon submission and prior to approval.

PI to sign additional agreement section and provide a head and shoulders photo of the PI must be attached in the space provided. This is required for ACT Licencing purposes for ANU project approvals to be an Animal Use Licence giving permission to use animals as noted in the project for breeding, research and/or teaching.

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Questions

If you have any questions or need assistance please contact the Animal Ethics Team at animal.ethics@anu.edu.au.

Australian National University

Appendix 1.

Purpose category	Description
A1	*Stock breeding* Breeding projects to produce new teaching or research stock. Include the animals used to produce progeny and any breeders or progeny culled in the process, NOT the final progeny themselves (as these will be counted under the project in which they go on to be used).
A2	*Stock maintenance* Holding projects for animals maintained for use in other projects. These animals may be maintained under an Animal Research Authority because they require special management. If they are not held under an Authority, (e.g. normal stock animals kept mainly for commercial production, but occasionally used in research) then they are only counted in the project where they are used for teaching/research. Examples: Fistulated ruminants which are maintained under a holding project, for use in other short-term feeding trial projects Non-breeding colony of diabetic rats held for research in other projects
A3	*Education* Projects carried out for the achievement of educational objectives. The purpose of the project is not to acquire new knowledge, rather to pass on established knowledge to others. This would include interactive or demonstration classes in methods of animal husbandry, management, examination and treatment. Examples: Animals used to teach examination procedures such as pregnancy diagnosis Sheep used in shearing demonstration classes for students; Dogs used to teach animal care to TAFE students Animals used in workshops to teach specific techniques and procedures
A4	*Research: human or animal biology* Research projects which aim to increase the basic understanding of the structure, function and behaviour of animals, including humans, and processes involved in physiology, biochemistry and pathology. *Examples:* Molecular biology studies Studies of hormone levels for reproductive physiology
A5	*Research: human or animal health and welfare* Research projects which aim to produce improvements in the health and welfare of animals, including humans. Examples: Animals used to develop a new diagnostic test for a disease Development of a painless method of spaying cattle Developing a new vaccine for animals or humans Production of biological products such as anti-sera, hormones and antibodies

A6	*Research: animal management or production* Research projects which aim to produce improvements in domestic or captive animal management or production. Examples: Developing an improved molasses/urea based supplement for cattle Determining optimum stocking rate for a pasture Evaluation of a calcium supplement for layer hens
A7	*Research: environmental study* Research projects which aim to increase the understanding of animals' environment or their role in it. These will include studies to determine population levels and diversity and may involve techniques such as observation, radio tracking or capture and release. Examples: Pre-logging or pre-development fauna surveys Fauna surveys for environmental impact studies Research into methods to control feral animals
A8	*Production of biological products* Using animals to produce products other than milk, meat, eggs, leather, fur, etc. Examples: Use of a sheep flock to donate blood to produce microbiological media Production of commercial anti-serum Production of products, such as hormones or drugs, in milk or eggs from genetically modified animals Quality Assurance testing of drugs but do not include animals which come under Purpose A10, below.
A9	*Diagnostic procedures* Using animals directly as part of a diagnostic process. Examples: Inoculation of day-old chicks with ND Virus to determine virulence Water supply testing using fish
A10	*Regulatory product testing* Projects for the testing of products required by regulatory authorities, such as the APVMA. If the product testing is not a regulatory requirement, e.g. it is part of a quality assurance system only, those animals should be included in the appropriate category selected from above. (This would be normally be Purpose A8 (Production of biological products) in the case of QA testing.) Examples: Pre-registration efficacy or toxicity testing of drugs and vaccines

Appendix 2.

Prolonged restraint or confinement: What constitutes 'prolonged' restraint will very much depend on the species and the experiment or situation. As a guide, in mice, prolonged restraint would include leaving a mouse restrained for longer than necessary during a procedure eg. leaving a mouse in a mouse restraint after blood collection until the next blood collection time point 10 minutes later. This would also include restraining a conscious mouse for an extended period of time for imaging (rather than anaesthetising the animal). Confinement includes housing animals in cages smaller than the standard, recommended size or floor area (as stipulated by state guidelines).

Reuse and repeated use of animals: Reuse of animals in this context refers to the use of an individual animals in more than one 'activity' as defined in the REMS system. An example of this would be an individual mouse being part of a six week drug trial, then subsequently being used in an 8 week long infectious disease experiment. ANU does not support the reuse of animals. Reuse and repeated use of an animal does not include an individual animal that undergoes multiple procedures (eg. anaesthesia, blood collection, injections) during one activity.

Unrelieved pain and distress including where the planned endpoints will allow severe adverse effects: Activities that cause unrelieved pain and distress would generally include any of the outcomes listed in the mouse score system at score 3 or 4, and includes weight loss of 20%, wounds covering over 25% of the body surface, large ulcerated tumours, and significant breathing difficulties. If reasonable supportive care, analgesia and treatment is not provided this would lead to unrelieved pain and distress. In terms of planned endpoints, ANU does not support animals to be kept at a score 4 even if considered a planned endpoint.

Appendix 3.

Procedure category	Description
P1	*Observation involving minor interference* Animals are not interacted with or, where there is interaction, it would not be expected to compromise the animal's welfare any more than normal handling, feeding, etc. There is no pain or suffering involved. *Examples:* Observational study only Wildlife survey using camera trapping with lure and/or white flash Breeding animals for supply, where only normal husbandry procedures are used Breeding or reproductive study with no detriment to the animal Feeding trial, such as Digestible Energy determination of feed in a balanced diet Behavioural study with minor environmental manipulation Pasture studies using grazing animals Teaching of normal, non-invasive husbandry such as handling and grooming Production of products, such as hormones or drugs, in milk or eggs from animals which are subject to normal husbandry procedures only
P2	*Animal unconscious without recovery* Animal is rendered unconscious under controlled circumstances with little or no pain or distress. Capture methods are not required. Any pain is minor and brief and does not require analgesia. Procedures are carried out on the unconscious animal which is then killed without regaining consciousness. *Examples:* Laboratory animals killed painlessly for dissection, biochemical analysis, etc. Teaching surgical techniques on live, anaesthetised patients which are not allowed to recover following the procedure No experimentation on living animals, e.g., animals killed painlessly for dissection, biochemical analysis, in vitro cell culture, tissue or organ studies Collecting blood or plasma from anaesthetised dogs prior to euthanasia Live animals euthanased for later scientific use, e.g., rats and toads for dissection

P3	*Minor conscious intervention* Animal is subjected to minor procedures which would normally not require anaesthesia or analgesia. Any pain is minor and analgesia is usually unnecessary, although some distress may occur as a result of trapping or handling. *Examples:* Injections (not drugs trials), blood sampling in conscious animal Minor dietary or environmental deprivation or manipulation, such as feeding nutrient-deficient diets for short periods Trapping and release as used in species impact studies Trapping and humane euthanasia for collection of specimens Trapping and humane euthanasia for feral animal control research Stomach tubing, shearing Performing ultrasound under sedation
P4	*Minor surgery with recovery* Animal is given appropriate regional or general anaesthesia with as little pain or distress as possible. A minor procedure such as cannulation or skin biopsy is carried out and the animal allowed to recover. Depending on the procedure, pain may be minor or moderate and postoperative analgesia may be appropriate. Field capture using chemical restraint methods is also included here. Examples: Biopsies Cannulations Sedation/anaesthesia for relocation, examination or injections/blood sampling Castration with regional or general anaesthesia and post-operative analgesia Implantation of microchip in horse after injecting local anaesthesia
P5	*Major surgery with recovery* Animal is rendered unconscious with as little pain or distress as possible. A major procedure such as abdominal or orthopaedic surgery is carried out and the animal allowed to recover. Post-operative pain is usually considerable and at a level requiring analgesia. Examples: Orthopaedic surgery Abdominal or thoracic surgery Transplant surgery Mulesing or castration without anaesthesia
P6	*Minor physiological challenge* Animal remains conscious for some or all of the procedure. There is interference with the animal's physiological or psychological processes. The challenge may cause only a small degree of pain/distress or any pain/distress is quickly and effectively alleviated. Examples: Minor infection Minor or moderate phenotypic modification Early oncogenesis Arthritis studies with pain alleviation Induction of metabolic disease Prolonged deficient diets Polyclonal antibody production Antiserum production Vaccination or drug trials

P7	*Major physiological challenge* Animal remains conscious for some or all of the procedure. There is interference with the animal's physiological or psychological processes. The challenge causes a moderate or large degree of pain/distress which is not quickly or effectively alleviated. Examples: Major infection Major phenotypic modification Oncogenesis without pain alleviation Arthritis studies with no pain alleviation Uncontrolled metabolic disease Isolation or environmental deprivation for extended periods Monoclonal antibody raising in mice
P8	*Death as an endpoint* This category only applies in those rare cases where the death of the animal is a planned part of the procedures and animals die but are not euthanased. Where predictive signs of death have been determined and euthanasia is carried out before significant suffering occurs, they may be placed in category P6 or P7. Examples: Death as an end-point does include: Lethality testing (LD50, LC50) Toxicity testing with death as a planned end-point without euthanasia Dose rate studies for feral animal control. Death as an end-point does not include: Death by natural causes (incidental to the scientific use) Animals which are euthanased as part of the project Animals which are euthanased on completion of the project Animals which are euthanased as a result of an unexpected adverse event Animals euthanased for dissection or for use as museum voucher specimens or Accidental deaths.
P9	*Production of genetically modified animals* This category is intended to allow for the variety of procedures which occur during the production of genetically modified animals. As animals in this category may be subjected to both minor and major physiological challenges and surgical procedures, this category reflects the varied nature of the procedures carried out. It effectively includes ALL animals used in GM production other than the final progeny which are used in a different category of procedure. Examples: Initial breeding animals for GM production Animals culled as part of the GM production process

Appendix 4.

Mice are to be housed in the Hugh Ennor Building, 117 Garran Road, Acton ACT 2601 under the care of the Animal Services division of the Australian Phenomics Facility (APF) ANU. The Hugh Ennor Building operates as a specific pathogen-free facility with a list of excluded pathogens. Staff work within the facility using established operating procedures and a hierarchy of traffic flows designed to reduce the risk of infection and cross-contamination of mice. A pathogen screening and health monitoring system is in place to detect the presence of agents that could compromise research. Mice are monitored daily by trained and competent animal care technicians to look for health concerns and to ensure high standards of housing and care are maintained.

Animal holding room environments are controlled by a Building Monitoring System (BMS) that maintains rooms at temperature of 20.5 °C (target range: 20-22°C) and humidity in the range 45-65%RH. The BMS is alarmed for temperatures below 16 oC and above 22 °C and for failures of critical plant and equipment. A back-up diesel generator in case of extended power outages can sustain normal operations for up to 2-4 hours and emergency procedures are in place for responding to alarms. The animal holding rooms are ventilated by HEPA filtered air at 15 air changes per hour and the 12-hour light/dark cycle using manual analogue light switches.

Caging for mice is Tecniplast Green line Sealsafe® Individually Ventilated Cages (IVCs) at 500cm2, or supplied with lifeboats to a maximum floor space of 610cm^2. Maximum number of adult mice allowed per cage is 5 mice < 30 g or 4 mice > 30 g. Standard bedding is 1/4" corn cob bedding with Alpha-twist nesting material included. Additional enrichment supplied can comprise of cardboard tunnels or plastic tubes, tissues, aspen nesting wool and wooden chew blocks. Cages complete with bedding are sterile autoclaved as complete closed units before supply to animal rooms. Additional enrichment added to cages is sterile autoclaved.

Mice are provided with irradiated breeder rodent chow ad lib which may be supplemented with autoclaved sunflower seeds. Water is provided through an automated watering system in which the water is pre-filtered, carbon-filtered, put through a Reverse Osmosis system and then Chlorine treated to 2-3ppm. The water Chlorine level is tested daily to ensure within 1ppm - 4ppm. In some cases, water is provided to cages in bottles with sipper lids, in which case sterile-filtered, UV-treated mains water is supplied, after autoclaving in bottles.

Sanitation and husbandry procedures follow recognized standards, with cage changing occurring on average fortnightly depending on the cage requirements. Technicians are trained on how to identify cages that require changing.

An electronic database system Rodentity, is used for recording mouse production and usage. This tracks mice from birth or arrival at the facility, through uses such as breeding, health screening, cryopreservation or supply to research ethics protocols until finally culled or exported to other facilities. Records for animals include genotypes, procedures such as blood collection and ethics protocol and gene technology approval numbers assigned.

Appendix 5

Useful websites

Description	Link
Compulsory animal ethics training	https://services.anu.edu.au/training/animal-ethics-training
AEC Submission dates	https://services.anu.edu.au/research-support/ethics-integrity/animal-ethics-submission-dates
Alternatives to animal research	https://services.anu.edu.au/research-support/ethics-integrity/animal-ethics-resources-training-support/alternatives-to-animal
Statistical support options	https://services.anu.edu.au/research-support/ethics-integrity/animal-ethics-resources-training-support
ANU Statistical Support Network	https://services.anu.edu.au/business-units/research-initiatives-and-infrastructure/statistical-support-network
AEC guidelines and standards	https://services.anu.edu.au/research-support/ethics-integrity/animal-ethics-policies-procedures-and-guidelines
AEC templates – monitoring sheets	https://services.anu.edu.au/research-support/ethics-integrity/animal-ethics-policies-procedures-and-guidelines
Use of drugs in research animals	https://services.anu.edu.au/research-support/ethics-integrity/specific-research-areas-0/use-of-drugs-in-research-animals