

ANIMAL ETHICS APPLICATION TIPS

Australian

National University



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 AEC members need to be able to understand the various experiences that an animal will be exposed to, including rest periods, transport, release 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 (SSN) 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. Ensure training, competencies and supervision information for each team member is included, along with what procedures they will be undertaking for the project being applied for.
- 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. The vets can also provide a pre-review, request this in REMS upon submission.
- 7. Make sure to check what permits and licences may be required for your work and provide this information in your application.
- 8. Ensure you have appropriate emergency procedures in place for work in the field. Options include the listing of a nearby veterinary clinic, rangers that are involved in the project etc.
- 9. 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.
- 10. Ask us! Contact the Animal Ethics Team at <u>animal.ethics@anu.edu.au</u> or the Vet Services Team at <u>vetservices.ris@anu.edu.au</u>.

Before Starting 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 <u>here</u>.
- Visit the <u>REMS SharePoint</u> 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.

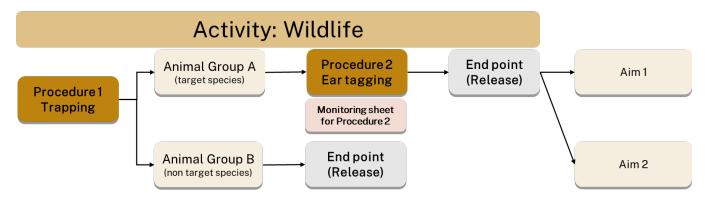


Figure 1. A diagrammatic representation of an example Activity, containing 2 procedures, and 2 different animal groups. The data collected from this Activity will help address Aims 1 and 2 in the Animal Ethics Protocol.

Check the Animal Ethics Submission Dates

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

We 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 3month extension period.

Completing your Application

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

This document contains some 'tip and tricks' for selected sections of the Wildlife 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 Animal Ethics Committee (AEC) a broad overview of the purpose of the protocol, 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 the 'Prepare' section.

Investigators

3.2 Role and responsibilities on the protocol

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

Top Tips

- Primary investigators and Nominees must be ANU personnel or have ANU affiliation.
- Ensure a person is allocated the role of Nominee. This person will be the back-up contact for the protocol should the Primary Investigator (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).

- For student projects, unless PhD student, students should be the Nominee and their supervisor the PI.
- If a student is listed on the protocol 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.
 - \circ $\;$ Their general experience with the species/type of program.
 - Their specific experience with procedures being performed.
 - Training
 - o Competencies
 - Supervision arrangements while obtaining competency for a procedure they will be working on in the project being applied for.
- 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, including who will provide training and who will assess competency.

Common Issue

• Lack of information provided on specific training, in particular for the advanced techniques referred to in the protocol, can make it challenging for the AEC to assess the application. The Code requires that investigators are competent in procedures they are undertaking or under appropriate supervision (Section 1.29) and the AEC requires confirmation that this is the case.

Project Description

5.1 Project design

The purpose of this question is to ensure that all members of the AEC can understand a general description of the proposed research and why the research is being planned. The AEC is made up of a mixture of individuals with different backgrounds; vets, scientists; animal technicians, animal welfare representatives and lay people representing the general public.

It is important that all the members of the AEC have a good understanding of the intention of your protocol, 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 AEC.

Top Tips

- Keep this to the maximum 500 words.
- Ensure it is truly a lay description aim your description to be for someone without a science background.
- Set out clear aims/objectives/hypothesis for your work.
- If this is a renewal of a previous protocol, make it clear how your work has progressed to this protocol.

• 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 issues

- Language is too scientific and needs to be in plain English.
- Clear objectives and hypothesis not provided.
- The growth of a project between historically approved protocols 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 protocol and provide information for the AEC to address the harm/benefit analysis that is integral to the AEC's review of the application.

You should use this opportunity to clearly state the expected benefits from the protocol. 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 Issue

• The impact and mitigation steps are often repeated rather than justifying the benefit of the work over the impact to the animal which the AEC 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 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).
- Further information on alternatives to animal research can be found on the ANU animal ethics resources, training and support website: <u>Alternatives to Animal</u> research

Common Issue

- 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 and the methods used to minimise the number of animals used to answer the scientific question.

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: <u>Animal Ethics: Resources, Training & Support</u>
- 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 AEC 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.

- 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 AEC 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 appropriate use of traps (set up time, covering of traps for weather protection, checking intervals etc).

Common refinements used at ANU include: training of individuals to perform procedures competently, the use of monitoring sheets, the provision of analgesia or use of anaesthesia for invasive procedures, not performing fieldwork in extreme weather, and use of traps in waterways that reduce bycatch.

Top Tips

- Monitoring or score sheets are required to be uploaded for Q11.1 as part of the section Other Details. For field work this may include the monitoring of animals post capture and release (where feasible) to assess any impact.
- The Vet Services Team can discuss and help develop refinements and monitoring sheets for your protocol, contact: <u>vetservices.ris@anu.edu.au</u>
- 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 protocols 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

- 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 protocols 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 the ANU Vet Service Team s if you think your protocol will include any of these 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 AEC a broad overview of the interventions being performed on the protocol, 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.

5.8 Will any types of animals be excluded from experimental activities? And 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 help identify the scope of the experimental program. Animals may be excluded because they are non-target species caught during fieldwork, or target species that are not the required due to age, gender, size etc.

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.

Animals

6.10 Describe the reason for choosing this animal

Please provide information on why the animals being used relate to the aims of the study. Reasons for inclusion may include: the species, and specific characteristics of the animal, e.g. the sex, age or size of the animal.

6.11.3 Expected mortality (If planning to breed)

This question relates to the expected 'background' mortality rate associated with keeping animals in captivity and during breeding. This may include common husbandry related diseases, perinatal death, dystocia, and fight wounds associated with breeding.

This does not include the mortality associated with procedures – this information can be outlined in the Activities section, under Q8.10 Cumulative Impact of Activities and Procedures.

Total animal number

Total animal number will appear automatically once animal groups/species are added to the Animals section. Please ensure that the numbers of animals detailed for each activity add up to the total number of animals requested (in Animals and Total Animal Number). If the number has not updated, please save the form and the numbers should update after saving the form.

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 AEC a step-by-step description of what will happen to each animal (or group of animals) in chronological order. This allows the AEC 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.
- Diagrams showing activity timelines are strongly encouraged and can be included in the rich text box or uploaded as a separate file (pdf, PowerPoint, word doc etc)
- Don't forget routine procedures such as individual identification procedures such as PIT tagging, ear tagging etc.
- Create the animal group first in REMS, then complete the activity to describe the experiment.
- Fully complete the activity section in REMS and press 'add group' to save.

Common Issue

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

8.3.1 Describe how wildlife will be captured and handled including whether traps will be used

In response to this question, please provide details of how animals will be trapped and how they will be handled. Please also see: Document 021: Wildlife Survey and Trapping Guidelines V1.0 (<u>Animal Ethics Policies</u>, <u>Procedures and Guidelines</u>) for further details.

To address this question consider:

- The type of traps used
 - Be specific. Provide photos of the types of traps, especially if they are made specifically for your project. Add details on how the traps may be designed for the specific species and how they may reduce by-catch. Include detail on any protection the traps may have e.g. lining to protect from hypothermia, external covering to stop water ingress etc.
- How many traps will be set and over what period of time?
 - This is crucial information to allow the AEC to assess if you have planned the trapping events appropriately. Include how many people will be checking the traps and this should make sense over the period of time and be feasible.
- How often will traps be checked &/or cleared?
 - The AEC expects that traps are checked very regularly. This should be specific to the species, type of trap and the environmental conditions.
- What is the safest time to trap and release these animals?
 - This will vary depending on the species and the time of year. Ensure you take into consideration weather extremes, breeding events, predator

presence etc. Be specific with restrictions you may impose (e.g. maximum/minimum temperatures etc).

- How will animals be restrained? (outline anaesthetic procedures if applicable)
 - Be as detailed as possible in this answer. If animals are housed in a bag for a period of time, or a transport container, include details on how the container is decontaminated between animals to limit the spread of disease.
 - Detail how long animals will need to be restrained for.

8.4 Are devices used to track movement of wildlife? And 8.4.1 Describe the devices that will be used

In response to this question, please provide details of what devices will be used and how they will be fitted, along with what monitoring will be performed post attachment to ensure adverse events can be identified.

Factors to consider include:

- The size and weight of the tracking device in relation to the target species. It can be helpful to attach pictures of what they look like.
- Detail if the tracking device has a 'weak link' and if not, why there is no weak link. Provide details on whether you have considered the potential growth/weight loss/reproductive status of the animal.
- If you have used the same/similar tracking devices in the past, detail any potential complications and how these will be minimised/managed if they occur.
- If the application is new, consider a pilot study perhaps in a captive environment, where feasible, to ensure there is minimal risk of snagging/complication.
- If tracking devices are used how will they be retrieved? If a tracking device ceases to be operational, what options are there to try to locate the animal and remove the device?

8.7 Provide details of the study group with approximate numbers per group

Please provide details of which species (entered in the Animals section) are included in the activity listed, and what number will be used. You can provide a written explanation, dot points, a table or upload a spreadsheet.

Please ensure that the numbers of animals detailed for each activity add up to the total number of animals requested (in Animals and Total Animal Number).

8.10 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 repeated handling, blood sampling and any expected adverse welfare outcomes (eg. injury, pain, misadventure, predation, mortality).

For fieldwork, consider the impact of the timing of activities and procedures eg. seasonality or time of day/night, and how this relates to normal behaviour such as breeding season or hunting/foraging.

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. Researchers are also encouraged to include animal emergency contingency plans for field work, for example, criteria for humane killing or euthanasia and where this will be performed (eg. a local veterinary clinic).

Top tips

- A timeline of the 'life story' of individual animals can be very helpful for the AEC to understand the cumulative impact on the animal. A timeline can be attached as a separate document in this section.
- If animals are to be transported and in held in facilities the 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.
- Where multiple trapping events are likely throughout an animal's life, the timeline should be detailed and the frequency provided. If the intention is to avoid multiple trapping/handling of the same animal, methods to avoid recapture on the same/subsequent trapping events should be detailed.
- If animals are released back to their natural habitat ensure that the risks of territory changes, fighting, predator and environmental conditions are all detailed and methods to mitigate these risks are listed.
- Include a description of expected adverse events for the activity including a mortality rate if interventions are likely to be high impact.
- Ensure that any changes you have implemented in previous protocols 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 AEC 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.

Procedure approval process

Procedures submitted with an Animal Ethics Application will be assessed at the same time as your animal ethics application. When approved, the procedures are approved for use as part of the approved Animal Ethics Protocol.

Top Tips

- ANU Animal Ethics AEC Guidelines or Standards are available, it is useful to refer to these (Animal Ethics Policies, Procedures and Guidelines).
- If you need to adjust how something is performed compared with these AEC approved guidelines, then this must be made clear in your protocol application (you can add this information to PR01 Procedure Variation).
- Don't forget to include any procedures required to identify animals such as ABBBS banding, or PIT tagging.
- Don't forget to 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 protocols 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 protocol 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: <u>Use of Drugs in Research Animals</u>

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 similar agents.

10.4 Dose rate

Please provide agent dose rates in the form of mg/kg (or similar).

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 ANU 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 AEC how animals will be monitored throughout their lifetime. This includes monitoring while held, or during and after activities are conducted. Depending on the activity, animals may require multiple monitoring sheets during their lifetime.

Top Tips

- Seek advice from the ANU 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 Animal Ethics Policies, Procedures and Guidelines)

Common Issues

• No monitoring sheets used during anaesthesia.

- Poorly designed score cards that do not have clear intervention points (eg. additional pain relief, or veterinary intervention required)
- 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.

Top Tips

- Consider all chemical agents used in experiments, and the potential exposure to research and animal care staff.
- Consider fieldwork and animal handling risks.
- If using isoflurane consider the risk of exposure to waste anaesthetic gases.
- 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

12.2.1 Where will fieldwork be located?

For Wildlife projects the location must be included for all work undertaken (including observational). Please provide GPS co-ordinates where possible if locations are remote and no specific address or name, if over large areas noting regions (eg Gippsland or Shoalhaven) and State or National Parks etc can be used. Private premises also need to be noted. You may also upload a map, or a spreadsheet or separate document if a large number of sites are being included.

Ensure for Q 12.1 each state or territory that work will be conducted in is listed (if Jervis Bay Territory please note this is a Federally managed area).

The same principles apply for describing where work will be undertaken overseas.

14.1 Will animals be held for any period of time under this protocol. And 14.1.1 Describe conditions under which animals will be held

In this context, 'held' refers to the short term confinement of animals, as well as keeping animals for long term care or breeding. For this question, 14.1, please include details of periods of time where animals are held that is outside of the routine care and husbandry that will be detailed in Q14.7

Animals may be 'held' while being processed in the field, or when animals are kept for a short period of time to ensure they are released at an appropriate time or during appropriate weather.

If animals are being held, please provide the approximate duration and reasons why holding the animal is necessary. Please also provide the details of the type of housing (eg. cage, calico bag, bucket), any bedding provided, stocking density if multiple animals are held together, measures taken to ensure animals are safe and comfortable (keeping cages in the shade, monitoring air temperature in the cage or water temperature in a tank, protection from predation).

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

14.7 Provide details of care

Please provide details of the day-to-day care of animals housed. This includes the location/facility name, cage set up, stocking density, cleaning regimes, any biosecurity measures, common husbandry procedures, monitoring sheets used and other relevant housing information.

Documents such as a husbandry handbook can be uploaded to the rich text boxes to address this question. Relevant SOPs may also be uploaded to the procedures section.

14.8 For remote/interstate/overseas field work a local vet for emergencies is required. Provide details below

The AEC is mainly interested in emergencies that may arise as a direct result of the research protocol.

The ANU expects wildlife researchers in the field to have options to deal with animal welfare emergencies. A veterinary coverage plan, that covers suitable treatment of animals that may be directly impacted as a result of the research activities, must be included in an approved wildlife animal ethics Project. Such plans should consider the availability of a veterinarian, the competency and knowledge of the field workers, the likelihood of adverse events and how they may impact animal welfare. The plan must include who may be involved in performing euthanasia should this be necessary, their training and a communication plan surrounding this requirement. In all situations, where an injured or ill animal is identified, veterinary advice must be sought immediately. Any variations to these requirements must be clearly identified in an approved animal ethics Project.

Projects that are remote may incorporate the need to train individuals undertaking fieldwork in at least one humane method of euthanasia as outlined in this Project.

Projects that are within reasonable distance of a veterinary clinic may nominate to make a written agreement with a veterinary clinic and submit this agreement with their application. An ANU vet must also be kept up to date with any events and treatment or actions undertaken and are also available for advice and discussion where required.

For Projects without a written agreement, the ANU vets must be contacted as soon as possible in the event of any animal welfare emergency and an action plan will be determined based on location and availability of resources. In some situations, physical support from the ANU vet may not be possible and advice may be provided to attend a local veterinary clinic for assessment, diagnosis and potential euthanasia.

The AEC understands that not all emergency situations can be predicted, in particular those that may not relate directly to the research Project. The AEC expects that common sense applies to relieving pain and distress in animals where possible. Options to follow up on finding animals in pain or distress may include contacting local wildlife groups such as Wires (NSW), ACT Wildlife (ACT) or Wild care (Queanbeyan region).

For further information please see: Document 016: Guidelines for Field Euthanasia of Wildlife V1.0 (<u>Animal Ethics Policies, Procedures and Guidelines</u>)

Licencing

List all licences and permits required for this project. Please note all licence/permit renewals for the project must be submitted to the Ethics Office upon receipt, or with Annual/Final Reports.

Please note if working within certain States, the Ethics office may also need to also provide research authorities/licence documents to researchers before research can commence.

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 prior to approval.

PI to sign off on submission and provide a head and shoulders photo of the PI must be attached in the space provided in the REMS protocol application form Investigator section. The photo can also be added into your profile section for easy downloading. This section is designed to meet ACT Animal Use Licencing requirements.

Questions

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



Australian National University

Appendix 1.

| Purpose category | Description |
|---------------------|--|
| A1 | <i>Stock breeding</i> 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 maintenanceHolding projects for animals maintained for use in other projects. These animalsmay be maintained under an Animal Research Authority because they requirespecial management. If they are not held under an Authority, (e.g. normal stockanimals kept mainly for commercial production, but occasionally used inresearch) then they are only counted in the project where they are used forteaching/research.Examples:Fistulated ruminants which are maintained under a holding project, for use inother short-term feeding trial projectsNon-breeding colony of diabetic rats held for research in other projects |
| A3 | <i>Education</i> 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 biologyResearch projects which aim to increase the basic understanding of the structure, function and behavior 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 |
|-----|---|
| Α7 | 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 | <i>Diagnostic procedures</i> 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. For wildlife, prolonged restraint may include animals being kept in traps or transport containers for excessive amounts of time, with the amount of time considered excessive relating to the species, trap type, weather conditions and other factors.

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. 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, nor would it include animals that are part of a capture-recapture 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 injury or disease that is life limiting. If reasonable supportive care, analgesia and treatment is not provided this would lead to unrelieved pain and distress. In terms of wildlife research, where possible interventions are often limited, euthanasia or humane killing may be required in these instances.

| Procedure category | Description |
|-----------------------|--|
| P1 | Observation involving minor interferenceAnimals are not interacted with or, where there is interaction, it would not beexpected to compromise the animal's welfare any more than normal handling,feeding, etc. There is no pain or suffering involved.Examples:Observational study onlyWildlife survey using camera trapping with lure and/or white flashBreeding animals for supply, where only normal husbandry procedures are usedBreeding 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. <i>Examples:</i> 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 |

Appendix 3.

| 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 as part of the project |
| | Animals which are euthanased on completion of the project |
| | Animals which are editariased as a result of an unexpected adverse event |
| | Accidental deaths. |
| | |
| P9 | * NOTE: Death as an endpoint research is not permitted at ANU. <i>Production of genetically modified animals</i> |
| P9 | 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 5

Useful websites

| Description | Link |
|------------------------|---|
| Compulsory animal | Animal Ethics: Training |
| ethics training | |
| AEC Submission dates | Animal Ethics Submission Dates |
| Alternatives to animal | Alternatives to animal research |
| research | |
| Statistical support | Animal Ethics: Resources, Training & Support |
| options | |
| AN Statistical Support | Statistical Support Network |
| Network | |
| AEC guidelines and | Animal Ethics Policies, Procedures and Guidelines |
| standards | |
| AEC templates – | Animal Ethics Policies, Procedures and Guidelines |
| monitoring sheets | |
| Use of drugs in | Use of Drugs in Research Animals |
| research animals | |
| | |