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. Attachments can help with this.
3. Justify your numbers – random number allocations or referring to ‘what has worked before’ is not sufficient and you need to be able to statistically justify the numbers you are requesting.
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 as the questions advance, clearly outline how you will minimise these impacts.
5. Detail the specific training those on the protocol have had, whether they are competent in the procedures to be undertaken.
6. Liaise with the vets and ethics team in advance of your application. They can provide advice on the application process and specific veterinary advice including anaesthetics/analgesics/dose rates etc.
7. Outline the monitoring for different stages of the animal’s lifetime. Provide specific score sheets for projects that may involve direct impact/pain or distress to the animals.
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 AEEC published standards and guidelines for advice on common procedures that may be undertaken. 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 animal.ethics@anu.edu.au or vet services team at vetservices.rsd@anu.edu.au.

# Beginning your application

Here are two top tips when beginning a new application in ARIES:

* Enter and save your name under the Investigator tab, otherwise you will not be able to search for/find your application when you come back to ARIES after closing the application.
* **Do not open ARIES twice in the same internet browser** as it causes information to be inadvertently transferred between protocol records. If you wish to copy and paste from a previous protocol application in ARIES, make sure you open ARIES in two different internet browsers to do so (e.g. Firefox and Chrome), or copy the text from a PDF or Word version of the protocol.

Header page:

Ensure the proposed start date is after the meeting date. It can take a couple of weeks for approvals to be processed post meeting especially if the AEEC has post meeting questions/requests, therefore this should be factored in when choosing the start date.

Make sure that the number of months between the start and end dates is equal to the number entered at 1.7 Main details tab. 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 with special conditions and only with good reason, subject to AEEC approval via submission of an amendment application. (See Main Details Tab note.)

If the protocol is replacing a previous protocol that is about to expire, please add this in under the text box heading “Any Other Comments” on the bottom of the page. Provide the expiring protocol’s number. This box can also be used to include information about licencing eg if a licence/permit application is currently in process, or any other information the AEEC needs to know which is not covered by the other questions.

Please note the Ethics Office will allocate an Ethics number after the application has been submitted and will notify you of this.

# Completing your application

### Generating a copy of your application

Before you press the Submit button you can generate a PDF of your application by clicking the “Print Form” button on the Header page, then click the Magnifying glass icon, then click ‘1) Click this link to open you external document’ , then right click ‘Save Page As’ to save the PDF to the preferred location on your computer.

### Signatures

The PI, Nominee and all investigators must sign the application. The signatures must be submitted by the AEEC Meeting date your protocol is assigned to.
When you create the pdf – there are two signature pages at the end.

The first page is for all investigators to sign confirming they have read the protocol and agree to procedures, their role and any amendments/conditions the AEEC may require.

The second page is the ACT licencing page for the PI to sign and a head and shoulders photo of the PI must be attached in the space provided.

Please email the signature pages as a pdf to the animal ethics team on animal.ethics@anu.edu.au.
E-signatures (as long as they don’t lock the pdf) or scanned signatures are fine to use.

### Questions

If you have any questions or need assistance with the photo on the signature pages please contact the Animal Ethics Team at the RSD Ethics Office on animal.ethics@anu.edu.au.

## THE PROGRAM

1.1 Introduction

This is not a question but an introduction to the AEEC process.

1.2 Lay description

The purpose of this question

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 mixture of individuals with different backgrounds, from vets and scientists to welfare nominees and lay people. It is important that all the members of the committee 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 lay description, keep this in mind throughout the entire application process and ensure that you define acronyms and complex ideas to assist the lay members of the committee.

Top Tips

* Keep this to the maximum 120 words.
* Ensure it is truly a lay description – aim your description to a year 10 high school student.
* A basic description of what your work is all about.

Common problems

* Language is too scientific.
* The information is about the disease they are investigating rather than their research specifically.

1.3 Objectives and Hypothesis

The purpose of this question

To allow the committee to review the scientific background of the application. This forms part of the harm/benefit analysis that is integral to the committee’s review of the application. (1.5, 1.15)

Top Tips

* It is great if you can set out clear aims/objectives/hypothesis for your work
* You can include the science but some general description is great for the committee members without science qualifications
* Try not to use abbreviations or if you do – please provide a description of their meaning in the first use.

Common Problems

Clear objectives and hypothesis not provided.

1.4 Originality

The purpose of this question

To allow the committee to assess whether the project is justified they must be satisfied that this work isn’t repeating work already completed and is establishing new information or working towards an improvement in human or animal health. (1.6, 1.7)

Top Tips

* If this is a renewal of a previous protocol make it clear how your work has progressed to this protocol
* If the work is the same it is important that you explain why it isn’t changing/progressing
* The committee wants to know that you aren’t merely repeating work already done or being done elsewhere and that your work is truly novel
* If the work is novel and you are unsure of the outcome or impact on animals you may want to consider a pilot study. Any pilot study must be detailed in the ethics application as per the Code (2.3.14)

Common Problems

* Researchers only address the originality to their own previous work and not its uniqueness compared with what else has been published.
* The growth of a project between historically approved protocols is not clear and there is no argument for progression of research.

1.5 Alternatives

The purpose of this question

To allow you to address the “Replacement” and in some way the “Reduction” parts of the 3Rs (1.5-1.7)

Top Tips

* The committee is interested to know how much you have looked into alternatives.
* Simply stating that this 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 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).
* Have you considered a systematic review – this is a focus of the NHMRC and other bodies at present and it would be useful for you to consider this – perhaps with some consultation with others and whether it can help answer some of your research questions. For more information on systematic reviews check this website <https://www.radboudumc.nl/en/research/departments/health-evidence/systematic-review-center-for-laboratory-animal-experimentation>

Common Problems

No acknowledgement of systematic review or other alternative options can make it look like the researcher hasn’t looked into alternatives.

1.6.i What impact with the Program have on the welfare of the animals involved?

The purpose of this question

To ensure that you have considered the risks that exist when performing your research with animals. This must be specific to your research. Welfare impacts include pain and distress, change in provision of food and water that may cause stress, restriction from normal behaviour, changes in environment and any discomfort that may be caused during the course of the project. (1.8-1.14)

Top Tips

* For each of the procedures undertaken the impact on the animals must be detailed in regards to their welfare impact.
* Where animals are subject to multiple procedure, the cumulative impact on the animals needs to be addressed.
* If a number of procedures are performed on a single animal it may be useful to provide a timeline of events the animal is exposed to which allows the committee to consider the cumulative impact on the animal.

Common Problems

* Don’t list the methods to minimise the impact here – this is what the next question is for.
* If this is a new experiment or using compounds not previously used in animals then you need to outline this fact and if the impact is unknown, this should be clearly stated.
* Researchers often don’t flag where animals undergo a number of procedures. This misleads the committee and does not allow them to consider the cumulative impacts on the animal which is a critical component of their review.

1.6.ii What will you do to minimise the impact on the welfare of the animals involved?

The purpose of this question

To allow you to address the “Refinement” part of the 3Rs. This answer should flow on from the risks/impact that you outlined in 1.6i and should address each of the potential impacts you have highlighted. (1.10-1.14)

Top Tips

* This allows for a description of the “Refinement” that will be undertaken.
* Include any score sheets
* Seek advice from the Vet Services Team on score sheet design
* You should aim to address all of the impacts you identified above 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 Problems

Score sheets should be clear to follow and as close as possible to the standard ANU Score Sheet

1.6.iii What considerations justify the impact the Program will have on the animals?

The purpose of this question

This is one of the most important aspects of your protocol. This allows the committee to perform a cost/benefit analysis of the impact of your work and your stated potential benefits of the research.

You should use this opportunity to clearly state the expected benefits to the species, humans, teaching, environment or knowledge. (1.5-1.7)

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.

1.7 Estimated Duration

The purpose of this question

To determine how long you intend to undertake this protocol. (1.30)

Top Tips

* Ensure that you enter the duration of the protocol in months not years (i.e. 36 months)
* Protocols can only be approved for a maximum of 36 months.
* It is helpful if you detail somewhere in your application what funding is secured for the protocol and how long it is intended to last. *(2.3.16)*
* If you don’t need to start the program immediately you can request a deferred start date.

1.8 Program Personnel/Investigator Tab

The purpose of this question

To detail the people who will be working on the protocol, their level of responsibility and their experience. (1.29, 1.31)

Top Tips

* Ensure a person is allocated the role of nominee. This person will be the back-up contact for the protocol 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).
* For student projects – Honours/Masters students should be the nominee and their supervisor be the PI, but if PhD student they can currently be either the PI or nominee.
* If student listed on protocol please indicate the student type ie. PhD, Masters, Honours etc.
* Ensure you detail all the following information for each person:
	+ Their general experience with the species/type of program
	+ Their specific experience with each procedure to be undertaken under the protocol or clearly define where they will not be responsible for undertaking a procedure.
	+ Any specific training courses they have completed including whether they have been assessed to ‘competency.’
	+ The year they last completed the compulsory animal ethics training (this requires a refresher every 5 years). If they are not up to date or have not yet completed this training you must list the date by which they will complete training.
* 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.

Common Issues

* Primary investigators and Nominees must be ANU personnel.
* Lack of information provided on specific training, in particular the advanced techniques referred to in the protocol.

2. Classification of the Program

The purpose of this question

The answers to this question address the regulatory and reporting requirements for the University. It also allows an assessment of the degree of impact the work undertaken will have. (1.10-1.14)

Top Tips

Ensure you consider each classification carefully.

* A minor operative procedure (also referred to as minor surgical procedure) is a surgery that does not penetrate or expose a body cavity or permanently impair physical or physiological functions (e.g. subcutaneous implants, skin biopsy)
* Surgery with recovery is surgery that penetrates and exposes a body cavity or a procedure that permanently impairs physical or physiological functions (this includes craniotomy, laparotomy etc.)
* Death as an endpoint is generally not approved. This is not where animals die unexpectedly but where you intend to let animals die without humane intervention at an agreed endpoint.

Common Issues

* Not indicating the accurate classifications.
* Underestimating the type of challenge/degree of impact on the animal.

3.1 Animal Species

The purpose of this question

This section allows you to assign your animals into specific groups. You are required to provide the expected number of animals to be utilised for your protocol. (1.15, 1.16, 1.17, 1.21)

Top Tips

ARIES is limited in how it can assign ‘groups’ and often the procedures for groups need to be repeated if you list each strain/species as a separate group. Consider using your ‘experiments’ to define groups.

Although the use of visual aids like the below don’t fit into this question, it does help you understand how to group animals without the need to repeat the procedures.

Common Issues

Over-estimation of numbers.

3.2 General Explanation (of numbers)

The purpose of this question

You must provide details on how the total number of animals was determined. This should include the statistical justification for the numbers requested and the number of animals used per experiment. (1.15, 1.16, 1.21-1.27)

Top Tips

* It is strongly recommended that you seek advice from the ANU [Statistical Consulting Unit](https://services.anu.edu.au/business-units/dean-higher-degree-research/statistical-consulting-unit) for determination of appropriate statistical methods for your research and that your advice from the SCU is referenced in this answer.
* 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 under the protocol rather than through the animal facility – please include breeding numbers, with a breakdown of the numbers to differentiate between the breeding and experimental numbers. It is also important to include details on what may happen to animals which are bred but may not be required for experiments.
* Where you have a number of experiments it is useful for the committee to receive a table explaining the numbers to be used. Unfortunately, ARIES does not accept the use of tables in the fields but this can be attached in Documents tab for the committee’s assessment.
* Ensure the dates are the same as per the Header page.
* A decision tree or flow chart defining how you will decide which experiments will go ahead and which will not can be very helpful, especially if you are requesting very high numbers of animals.
* Do not try to underestimate down to the lowest possible numbers per experiment – 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.
* You do not need to complete the question “Total number approved” as this is for the ethics office to update on approval of the application.

Common Issues

* Lack of description of statistical design.
* Very large numbers of animals requested without any clear justification/reasoning that makes sense to the non-scientific members of the committee.

3.3 Location of animals during the Program

The purpose of this question

All areas for housing animals or where experiments/procedures are being performed must be completed. (3.2)

Top Tips

* The animal facility may have a general description for the day to day housing for biomedical animals that you can reference.
* Ensure that experimental areas are included as well as areas where breeding and long term holding is undertaken.
* Where transfer of animals is required it is handy if you include references to acclimatisation periods here or in the procedural section. You can refer to the ANU Acclimatisation Guidelines (yet to be published) for advice on appropriate periods.

Common Issues

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

4.1 Procedures for each group

The purpose of this question

To determine what specific procedures will be undertaken and allow the committee to assess how each procedure is undertaken and look at the specifics. (3.3)

Top Tips

* If ANU Central Guidelines or Standards are available, it is useful to refer to these (<https://services.anu.edu.au/research-support/ethics-integrity/animal-ethics-policies-guidelines-and-forms>).
* If you need to adjust how something is performed compared with these AEEC approved guidelines, then this must be made clear in your protocol application.
* Include the age and sex of the animal for each procedure.
* If multiple procedures are being undertaken, then a timeline of events for each animal can be useful for the committee to assess the potential cumulative impact on the individual.

Common Issues

* Vague responses without provided details on the steps within a procedure.
* Lack of detail that requires the committee to make assumptions on how a procedure is undertaken or leads to many further questions being asked in the Q&A process.
* 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).

4.2 Substances not including anaesthetics and neuromuscular blocking agents

The purpose of this question

To ensure all compounds being provided to animals are listed in the protocol. (3.3.8-3.3.15)

Top Tips

* Ensure your drug doses are accurate and within best practice guidelines.
* Consult with the ANU Veterinary Services team where you are unsure on appropriate drugs or doses.

Where novel compounds are being utilised ensure there is sufficient information provided for the committee to assess the compound in terms of risk. In particular where Non-Pharmaceutical Grade Compounds (NPGCs) are being utilised ensure you address the specific factors as listed in the relevant ANU documents (<https://services.anu.edu.au/research-support/ethics-integrity/animal-ethics-policies-guidelines-and-forms>)

4.3 Anaesthetic agents used

The purpose of this question

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. (3.3.8-3.3.15)

Top Tips

* Double check your dose rates and seek veterinary advice where you are unsure or if you are undertaking a new anaesthesia combination.
* Include the % of any inhalational anaesthetics and the flow rate for oxygen/gas to be provided simultaneously.
* Separate the doses for induction and maintenance.
* Refer to or attach a specific procedure where relevant.

Common Issues

* Lack of information and detail provided.
* Poorly written dose rates that do not adequately explain the anaesthetic procedure.

4.4 Neuromuscular blocking agents used

The purpose of this question

To ensure all compounds are listed. In particular, neuromuscular blocking agents come with unique risks of animals being restrained whilst still conscious and able to feel distress/pain therefore they are considered separately. (3.3.14)

Top Tips

Ensure the use of such agents is well justified in the protocol.

****Common Issues****

None reported to date, as these agents are rarely used.

4.5 Extent and method of supervision of animals during experimentation, including methods to be used for assessing and preventing pain and distress: This should include method and frequency of monitoring animals before, during and after procedures and should also detail what will be done if a problem is identified.

The purpose of this question

To detail the monitoring that will occur during the experimental period, before experiments begin to assess suitability and after experiments (this may be during a procedure, across many days/weeks or for the life of the animal where appropriate). (3.1.20-3.1.25)

Top Tips

* Utilise the ANU central standard approved Monitoring Score Cards where appropriate for rodents (<https://services.anu.edu.au/research-support/ethics-integrity/animal-ethics-policies-guidelines-and-forms>)
* Seek advice from the ANU Veterinary Services Team if your protocol has the potential for moderate to severe impact on animals.
* For surgical procedures or during the use of anaesthetics ensure the frequency of assessment of the depth of anaesthesia and welfare of the animal is noted. A specific score sheet during anaesthesia may be of benefit. The ANU Veterinary Services Team can provide templates for these and they are available on the ethics website.
* It is useful to define who will be responsible for the monitoring and when (eg research group on day of procedure and animal care staff thereafter etc.)

Common Issues

Poorly designed score cards that do not have clear intervention points or humane end-points detailed.

4.6 Following surgery, arrangements made by the investigators for immediate and continuing post-operative and/or post-procedural care, including details of restraint, housing and analgesics to be used.

The purpose of this question

To allow the committee to review the manner in which the risks to the animal will be monitored after they have been exposed to any procedure or change in conditions. (3.3.17-3.3.20)

Top Tips

* Ensure there are monitoring score cards in place.
* List the options for pain relief or actions to be taken if animals show a slow recovery or ongoing pain or distress.

Common Issues

* Lack of consideration of animals at the end of survival procedures including suitable pain relief options and monitoring requirements.
* Monitoring of animals left to animal care staff who may not understand or know what procedure the animals have experienced and the relevant risks and actions.

4.7 Provide details of the planned end-point for individual animals in the experiment and reasons for its choice. Are any animals to be used again and if so why?

The purpose of this question

To detail the end of experiment and allow the committee to assess any repeat experiments and therefore the ‘life impact’ on the individual animals under the protocol. (2.7.4 v, 3.1.26-3.1.28)

Top Tips

* If animals are to be re-used this requires specific outlining and justification in the protocol.
* A timeline of the ‘life story’ of individual animals can be helpful for the committee to understand the cumulative impact on the animal. This can be attached as a separate document.
* 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.

Common Issues

Re-use impact is underestimated by the research group.

4.8 If to be held at the University please detail length and justification for holding for this length of time.

The purpose of this question

To assess the requirement for holding animals that may not be under ‘active experimentation’ or require prolonged holding for experimental reasons.

Top Tips

* Animals are not to be held for prolonged periods without justification. Animals should be ordered/held for a specific reason. This should be outlined in the protocol.
* Rodents that are maintained past 12 months of age must have specific justification on the ethics protocol.

Common Issues

Researchers don’t understand the welfare implications of maintaining aged animals or holding animals beyond the planned endpoint.

4.10.1 If animals are to be killed, what method is to be used?

The purpose of this question

To determine the method that animals will be killed and allow this to be assessed by the committee. (3.3.45)

Top Tips

* If there are a few different methods, it is important to identify which method will be used in which situation.
* If using overdose of anaesthetic, it is necessary to undertake a secondary method of killing afterwards.
* Some young animals require special consideration so take this into account.

Common Issues

Procedures for some methods may be out of date – refresh knowledge by referring to the central SOPs at <https://services.anu.edu.au/research-support/ethics-integrity/animal-ethics-policies-procedures-and-guidelines>.

4.10.2 If animals not killed, what happens to them?

The purpose of this question

To determine the outcome of any animals not killed at the end of the experiment or the expiry of the protocol. This is often an important question for wildlife studies in particular. (3.4)

Top Tips

* Provide detail on the ongoing care and welfare management of any animals that are not killed.
* For all species that are held in captivity consider rehoming options (this would require consultation with the AEEC and University).

Common Issues

5 Are there any health risks to other animals or staff? If so, explain the nature of the risk and precautions to be taken.

The purpose of this question

To ensure that risks to staff and researchers, including animal care staff, veterinarians and other members of staff, are aware of the risks of the project and that adequate risk assessment has taken place. It is part of the responsibilities under the code to highlight work health and safety risks (2.1.8 vii)

Top Tips

* Consider all chemical used in experiments, 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.

Common Issues

Underestimating or underreporting of risks.

6 Is it the intention of the investigator that the findings of the program be published in their entirety?

The purpose of this question

To ensure that the intention is that information gained as part of the work being undertaken is published and the use of the animals is not wastage.

To allow the committee to review the intention of the research group to publish all findings, whether negative or positive. (Best practice methodology, 1.15-1.17)

Top Tips

Outline what you will do if your results do not support your hypothesis – will you publish negative findings?

Common Issues

Lack of detail and consideration for the intention of the question.

7 Any other comments

The purpose of this question

To allow research groups to add in other relevant information that may not form the answer to any of the above questions.

Top Tips

This can be used to convey any information that you haven’t had the opportunity to include in the rest of the protocol that you think is relevant for the committee consideration.

Common Issues

None.