

## **Guide to completing the 'Project Description Animal Care and Ethics Committee'**

### **Introduction.**

This document explains and contextualises the questions asked by the **Project Description** required to be submitted to the Animal Care and Ethics Committee (ACEC, the Committee) at Charles Sturt University (CSU).

The Project Description form directly addresses the **practical** and **ethical** aspects of the use of animals for scientific purposes. It is the medium by which the investigator can best advance **justification** for the use of animals and let the ACEC know exactly how the animals will be used.

As with any form there are limitations and expectations that have shaped its nature- it must capture information related to a wide range of activities, involving many different species. The form also needs to gather information that is essential for the NSW government, governments in other jurisdictions and the University. Because of this, sometimes it can appear that information being requested is of questionable relevance- every opportunity has been taken to ensure that only necessary information is collected. The Research, Integrity, Ethics and Compliance Unit (RIECU) is committed to continuous improvement and welcomes constructive advice at any time. If you have any input or questions, please contact the Governance Officer (GO) or the Animal Welfare Officer (AWO).

Exemplars are provided for some questions where appropriate- these are not exhaustive nor prescriptive and should be regarded as suggestions and guidance only.

Text in blue is quoted from the Code unless otherwise stated.

Any questions about the forms or this guide should be directed to the Animal Welfare Officer (AWO) or the Governance Officer (GO).

Please note that the Project Description is **one of two documents** that require completion and submission to the Animal Care and Ethics Committee before any animal research can commence. The other document is the '*Research Proposal Animal Care and Ethics Committee*'. **Both documents must be completed and submitted to the Animal Care and Ethics Committee at the same time.** Please note that this Project Description is for research only and does not apply to teaching activities. There is a separate form for teaching proposals: '*Teaching Project Description Animal Care and Ethics Committee*'.

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#### *Quote from the Animal Research Review Panel Model application form:*

*'The application should therefore focus on what is happening to animals and what is being done to ensure their well-being. It is important that this information is presented in a way that shows clearly what is happening to individual animals from the beginning to the completion of a project. The impact of procedures needs to be clearly detailed.'*

*The investigator should provide a step by step examination of all treatments (substances, dose rates, routes, volumes, anaesthetics, surgical procedures etc.) and the expected effects. **Flow charts or sequence of events tables are often of assistance.** In addition, factors that will impact on animals such as housing (type, duration, opportunity for social interaction) should be considered.'*

*The application should also explain clearly why the use of animals is justified, why the species and number of animals have been chosen and that the qualifications of personnel are suitable for the procedures to be performed.'*

*It is important for applicants to remember the composition of the ACEC. **Applications must be written primarily for an interested, intelligent person without a scientific background, not for a specialist.** The use of specialist language is not helpful to the committee and may delay processing of an application while explanations are sought.'*

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## **Section 1. Project details.**

Describe the project aims in lay terms, i.e. make it clear what you intend to achieve? Use language that someone with a non-science background would understand.

There are two important aspects to this question. The first is the need to use lay language and the second is the underlying reasons for undertaking the project.

Lay language. The oversight model regarding the use of animals for scientific purposes in Australia specifies the involvement of community representatives. The role of non-scientists is integral to this model- the community presence provides ethical scrutiny and consideration that is divorced from any potential institutional allegiance. Non-scientists can also provide a wider representation of community concerns and perspectives regarding the scientific use of animals. Variants of this model operate worldwide.

It is therefore **essential** that the project can be described in plain language/lay terms. This can be challenging and require considerable effort on the part of the investigator. The more complicated the project, the more intelligent and thoughtful the required effort becomes. The more complex the projects, the more effort the applicants must put in to deconstruction of concepts and simplification of language. These skills are often developed when practising sound teaching in a highly technical environment. The same skills applied to teaching undergraduates (especially in their early years) are applicable in producing lay summaries.

Some aspects to consider when writing the lay summary:

- Your audience comprises lay people and those with scientific/veterinary backgrounds. However, even those with scientific/veterinary backgrounds may not be familiar with your discipline area and/or the species involved. It is **easy** to confuse with jargon and tech-speak. It is **much more difficult** and **takes far more skill** to communicate complex ideas and techniques using '*normal*' language
- Use **plain** language wherever possible and, where not possible, provide definitions in plain language.
- It is not always possible to avoid the use of some **jargon** and/or **abbreviations** and/or **acronyms**. **Jargon** may have developed so that discipline-specific information can be communicated without confusion or to assign a word/phrase that cannot be described easily using common terms. **Abbreviations** and **acronyms** have usually developed to enable more concise communication. If jargon and abbreviations cannot be avoided or the alternative is not practical (scientific abbreviations/acronyms may well represent very long/unwieldy phrases), then they should be explained when first used or in a glossary.
- There are multiple websites with information on using plain language. Suggested search terms include: '*plain language in science*', '*lay language science*', '*lay language veterinary science*' and so on.
- Some sources suggest pitching the summary at a level of an intelligent year 10 student. Although this might be a useful guide, it is probably aiming a little low. Another suggestion is to aim at the level of an interested, intelligent adult without scientific training.
- Only scientific terms in common use should be used wherever possible.
- Avoid made up words or words that possibly only exist in the confines of a select group e.g. '*stealthification*', '*stealthy*', unless you define them first.
- **It is often a useful exercise to ask someone from outside your discipline area and/or without a scientific background, to read through the summary and feed-back how comprehensible they found it.**

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*Bottom line with lay language: you are trying to ensure that the reasons for doing the research are clearly presented. It is to your advantage to spend the time and effort to make your message as accessible as possible.*

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Make it clear what you intend to achieve. Why are you undertaking the project? What are the reasons that this research is necessary? There is some overlap between this question and the next one in that you will be describing the anticipated outcomes and what benefit these outcomes might provide for other animals, humans and/or the environment.

Provide a **rationale** and **justification** for why it is necessary to use live animals to achieve the aims described in (a), rather than non-animal methods? It is inherent in applying the principle of Replacement that the use of animals is justified. Justification involves a balance of the expected benefits of the project against the welfare cost to the animals involved.

This question is aimed at eliciting the justification for the project so that a decision can be made about the ethics of animal use. It is less concerned with why you have chosen the species/breed/genotype/phenotype etc than with **why** the expected **benefits** accruing from the project **justify the use of animals at all**.

The detail regarding types and numbers of animals is addressed in sections 2.1 and 2.2 of this form.

This is the section in which you should:

- Explain why this project is valuable in terms of its potential benefits to animals and/or humans and/or the environment.
- Explain why you consider the benefits to animals/humans/the environment outweigh the welfare cost to the animals involved.
- Following on from the point above, if the project involves **basic** research then the knowledge that this research might uncover, and how this could lead to further projects, should be described. It is important that the value of the project is made clear, so that this value can be weighed against the expected impacts on the animals. Basic research can sometimes be difficult to justify if it is not given appropriate context and if its potential to underpin further research or be applied is not adequately described.
- Explain why live animals need to be used to explore the hypothesis (eses) being proposed.

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*An obligation to respect animals underpins the Code. This obligation brings with it a responsibility to ensure that the care and use of animals for scientific purposes is ethically acceptable, balancing whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits to humans, animals or the environment.*

*The use of animals for scientific purposes must have scientific or educational merit; must aim to benefit humans, animals or the environment; and must be conducted with integrity.*

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Provide a summary of the research plan that includes: overall, this section does not have to answered point by point- often the information will be more naturally presented in a combined form e.g. the fact that anaesthetic is used is part of the '*experimental design*' but the details about the regime implemented are part of the '*procedures involved*'. These are more easily described together.

It is important that you are satisfied that you have addressed the four areas in this section (background/references, experimental design, procedures involved and sequence of events).

It is important that you provide sufficient detail so that an independent person could replicate your intended research. Reproducibility is an essential component of sound research e.g. Gaskill and Garner (2020), Smith et al (2018).

The overall aim of this section is that the **Committee understands the mechanics of the project, the timelines involved** in the project, **the context of the project** and when and **what happens to the animals**. *The animal's care and use must be accounted for from recruitment into the project to retirement from the project.*

Projects that are complicated will benefit by having **both text and graphic descriptions**. Demonstrating multiples of time points, treatments, experimental units/groups, procedures etc. using graphics such as tables or flowcharts can be extremely helpful in assisting the Committee's understanding of what the project entails. They can also be a useful exercise for the investigator in refining processes and educating team members.

Background to the experiment, including relevant references. What is the (brief) history and context of the proposed project? How does it fit in with current research directions, what previous research supports the hypothesis, what questions does it seek to answer? What is the broader context in which this project exists?

What is a 'relevant reference'? Ultimately this will be based on your professional judgement. In general, the quantity of references is not significant (you are not preparing a thesis) but the quality is. The quality of the reference is linked to e.g. its direct relevance, its contribution to the hypothesis, the ranking of the journal and so on.

Only key references should be included where possible- rather than include references as in an abstract or paper it is more important that they are used to support the **main** contentions of the project.

If your summary includes contentious or extraordinary elements (e.g. '*an antiprotozoan drug may have curative effects against viral infections*') then more specific references to support these elements would be appropriate.

If the project is based on multiple findings in a particular area, then the references should be those most proximate to the direction and aims of this project, rather than those underpinning the entirety of the research environment.

EXAMPLE: A project examining the effects of wind turbines on reproductive fitness in a species will require some specific references (if they exist) to support the argument that this is an area of valid research.

EXAMPLE: A project examining the effects of feed supplements is not likely to require multiple references supporting the general effects that feed supplements can have, but may require some backgrounding references for the class of supplement being trialled.

Any project that involves novel surgical, therapeutic, or diagnostic techniques will require specific, relevant references.

EXAMPLE: The use of novel radioactive isotopes or the use of established isotopes in a novel manner, would require specific references supporting the contention that they are fit for the stated purpose of the project. If no such specific references exist then the researcher would need to have references that support and/or inform their decision-making regarding their experimental use.

The experimental design, e.g. treatment groups, timing, endpoints. This detail will obviously vary greatly between projects. This is the information that describes the mechanics of the experiments- the '*what, how, how many, how long*' and so on. The detail given will be broad for items such as procedures e.g. you might state that the animal will be anaesthetised, but the detail about the anaesthetic regime can be answered in the following question. You could also combine the two elements if that makes it more readable.

The procedures involved, including any drugs, dosage and administration routes that will be used.

Clear, concise descriptions of the physical procedures that will be undertaken should be included here. SOPs should be referred to where relevant- this may save time for the applicant.

Where the nature of the procedures inherently involves the application of professional judgement by someone with appropriate training and expertise, then a covering statement addressing this should be included. A prominent example of this situation is when sedation and/or general anaesthetic is involved. The proposed regime should be included (with any options likely to be employed) along with a covering statement. Suggested text for a covering statement in this instance is- '*The anaesthetic regime stated will be followed where possible. However, in the interests of animal wellbeing and safety, and recognising that peri-anaesthetic contingencies can arise, the investigator(s) will access a range of options for induction and maintenance of general anaesthesia, local anaesthesia, analgesia and physiological maintenance. Including a range of options, rather than a rigidly prescriptive protocol, ensures that the attending veterinarian can appropriately exercise their professional judgement in addressing inevitable biological variations.*' A covering statement such as this attempts to capture the complexities of the sometimes minute by minute decision making inherent in some procedures, without the investigator having to address every single contingency in the application.

The entire sequence of events that the animal would be subject to, including timeline. This should include the following phases: acquisition, maintenance, and husbandry including: feeding, health care and social environment related provision (if using a social species), and the fate of the animals post-use or following withdrawal from the intended research. This information will allow the Committee to a) understand in detail what will happen to the animals and b) make a judgement about the cumulative effects of the project on the animals.

References:

Gaskill, B.N. and Garner, J.P. (2020) *Power to the People: Power, Negative Results and Sample Size*. Journal of the American Association for Laboratory Animal Science Vol 59.

Smith et al (2018) *PREPARE: guidelines for planning animal research and testing*. Laboratory Animals Vol. 52(2) 135–141

## **Section 2. Ethical considerations.**

### **Replacement**

Provide an explanation of why animals are needed for this project and why this species/age (range)/sex has been chosen. Explain which alternatives you have considered and why they are not suitable for this project. This section allows the investigator to explain why the particular animals being recruited are the most suitable for the proposed project.

It is incumbent on the investigator to be aware of current information regarding alternatives to animal use and to explore any that might be suitable. This awareness and exploration should be recorded in this section with explanations as to why you have decided to use the animals selected. There are multiple links to resources on the Animal Ethics webpage.

In many projects live animals are the only acceptable model due to various factors. Examples include: the complexity of physiological/multisystemic interactions, inability of non-animal alternatives to replicate or produce the data being sought. If this is the case, this should be stated and, if possible, supported by key references.

### **Reduction.**

Explain why the proposed number of animals is required. Your explanation must include the statistical basis for the number of animals and, if possible, a power analysis with alpha value. Power analysis is a suggestion only- if there is a better way of demonstrating the statistical basis for the number of

animals needed, then that should be provided. It should be noted that although there can be situations where power analysis is not suitable, it is often referred to as the 'gold standard'.

Although the overall aim is to use as few animals as possible, the number must be sufficient to provide valid statistical outcomes. With this in mind, it is equally important not to use too few animals- if the number used is insufficient to support robust statistical analysis then the project may fail and the animals used have been 'wasted'. Repeating a project because of poor experimental design can ultimately result in more animals being used than otherwise would have been the case.

The CSU Research Office offers statistical support please go to :

<https://research.csu.edu.au/research-support/data-methods-and-tools/specialised-units/quantitative-consulting-unit> for more information.

**N.B. when nominating the number of animals to be used, ensure that you have accounted for anticipated losses**

**Another consideration is that keeping the number of animals used to a minimum should not impose higher welfare costs on those animals that are used.**

Selected references:

Charan, J. and Kantharia, N.D. (2013) How to decide your sample size when power calculation is not straightforward. Journal of Pharmacology and Pharmacotherapeutics Vol 4, October-December 2013 <https://www.nc3rs.org.uk/news/how-decide-your-sample-size-when-power-calculation-not-straightforward>

Ricci, C. Baumgartner, J. Malan, L and Smuts, C.M. (2020) Determining sample size adequacy for animal model studies in nutrition research: limits and ethical challenges of ordinary power calculation procedures, International Journal of Food Sciences and Nutrition, 71:2, 256-264, DOI: 10.1080/09637486.2019.1646714

Indicate if animal tissue will/can be shared with other investigators? If so, provide details. The sharing of tissue is strongly encouraged as it allows maximum use of the animals recruited for the project, thereby potentially reducing the number of animals otherwise required. Tissue may be harvested from either live or dead animals. It is possible that you will not know the details of sharing the tissue- for example if it is to be bio banked. If so, this should be stated.

**Refinement.**

List all experimental and other factors that may impact negatively on an animal's welfare e.g. the acquisition process, the actual procedures being performed, analgesia, being removed from conspecifics/housed singly, being transported, being returned to pre-use environment or termination/disposal. For each identified factor, state how you will minimise the negative impact on the animal(s).

This section will usually be straightforward as most elements that might have negative welfare impacts will be readily identified. If appropriate environmental enrichment should be employed to minimise negative impacts and maximise positive states.

There may be some areas where the impacts are not as obvious. Some examples:

- Persistence of fear pheromones in studies using multiple individual subjects.
- Turnover of staff members during a project can affect some species e.g. rodents
- Normal human behaviour and conduct that can be anxiogenic. Examples include scents from perfume/aftershave/deodorants in rodents; large scale body and arm movements in most animals, particularly small carnivores; loud/sudden noises, and using sharp, rapid movements. Some animals may also be intimidated or made anxious by the way that people present- dogs can be particularly sensitive to the height of people (especially if they are standing over them), facial hair, spectacles in general and sunglasses in particular and clothing that breaks up or presents as unfamiliar the shape of the human body (especially

hats). In all of these cases the mitigation of impact will be a matter of managing the human participants and ensuring that they are well versed in species behaviour.

### **Special ethical considerations.**

Most projects will **not** have special ethical considerations. Special ethical considerations arise when the **project design does not allow for the mitigation or amelioration** of recognised adverse conditions and/or other negative welfare impacts. In most projects this will not apply, but there are some cases where, for example, it may be required that pain is not mitigated or ameliorated. In projects such as these, a case must be made to justify the lack of mitigation or inability to ameliorate.

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*1.9 Practices and procedures used for the care and management of animals must be based on current best practice that:*  
*(i) takes into consideration the relevant aspects of species-specific biology, physiology and behaviour*  
*(ii) is based on the best available scientific evidence (or, in the absence of scientific evidence, accepted practice), which includes the potential adverse impact of conditions and procedures on the wellbeing of the animals*  
*(iii) includes strategies to minimise adverse impacts.*

*Special ethical consideration and AEC approval are required where these conditions are precluded by the requirements of a project or activity.*

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**Re-use of animals.** Re-using animals can be part of the application of the Reduction principle. By animals being re-used the total number of animals used is decreased. However, re-use of animals can increase the overall welfare impact on individuals. **This section helps the Committee to make informed decisions about the cumulative welfare impacts on individual animals** if they are re-used in projects. If you are aware of specific details of other projects that animals have been involved in, then these details should be provided.

In the majority of cases, due to privacy and administrative requirements, you will not be aware of specific details- you should state this, but still acknowledge that there is a reasonable possibility that the animals in your project have been used in previous projects. This is especially pertinent in the case of animals held as standing herds/flocks by CSU- sheep and horses.

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*The wellbeing of animals used for scientific purposes must be considered in terms of the cumulative effects of the animal's lifetime experience.*  
*(Governing principles)*

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*2.3.15 When considering approval for the reuse of animals, the AEC must take into account:*  
*(i) the pain and distress, and any potential long-term or cumulative effects, caused by previous activities and conditions*  
*(ii) the time allowed for recovery of the animals between activities*  
*(iii) whether an animal has fully recovered from the previous activities*  
*(iv) the pain and distress likely to be caused by the next and subsequent activities*  
*(v) the total time over which an animal will be used.*

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