Animal Ethics Committee Application Guide

The aim of this guide is to assist investigators by providing them with the necessary background and understanding so that they can complete the AEC application form in a way that will allow the AEC to approve it.

This guide provides:

- General advice on filling in the application
- A list of common reasons AEC application approval is delayed or not provided
- A question by question guide to answering each question,

Each question in the application is asked for a reason. Investigators are required by the Code to provide certain information to the AEC in order for the AEC to be able to consider and hopefully approve a project. The questions are designed to prompt investigators to provide this information. All questions are necessary and the appropriate sections of the Code are cited in the guide in italics in the appropriate questions.

The AEC's forms are reviewed by the regulator to ensure we address each of these requirements of the Code.

General Advice on Applying to the AEC

The AEC members volunteer their time to be on the committee, most have other jobs as well as social and family commitments. Their role on the AEC usually takes about 2-4 days (depending on the meeting load) out of their month and they are not paid. They attend training, facility inspections, review over 200 applications, 500 amendments and even more reports as well as other items every year and without them, you would not be able to do your work.

They do their best to understand your applications and your research, but applications that use complex language, abbreviations, reference previous documents and papers or are lacking necessary information make their roles more difficult and increase the time they need to spend on your application. All the information required to read, understand and hopefully approve your applications need to be in the application document or in referenced SOPs available to them. You may think they remember your previous application from 3 years ago, and they may, but you are one of hundreds so it is unlikely. If you reference a previous application or use complex language it usually means they have to spend extra time finding documents or googling to find definitions, so please consider this when writing the application. In general, if they can't understand an application they will reject it, or send it back for clarification, delaying your approval and your research so if you want it approved write it with the AEC members in mind.

Answers to questions must be in lay language that can be understood by people with no scientific background. The AEC membership is prescribed to include a diverse group of people from a variety of professional backgrounds and it's unlikely that any person will have the knowledge or experience to understand your field to the degree of understanding of people working in your field. So:

a. Keep language simple (without being patronising)
b. Don't use abbreviations or acronyms unless you expand and explain them (including the names of schools and divisions)

c. Explain any technical terms that you use, either in the body of the application OR attach a glossary of terms and acronyms/abbreviations
d. Use diagrams, figures, tables (especially to show groups and animal numbers) whenever possible to help explain difficult concepts such as metabolic pathways, anatomy, surgical procedures, experimental design, caging or equipment.

Seek advice or ask to have your application reviewed before submission. Monitors have been selected in each area to review applications and make comments to address any issues your application may have before it goes to the AEC. The Animal Welfare Officer (who is a vet) is also available and can be contacted to help fill in the forms or provide advice on any issues you have with the process including procedures, the use of anaesthesia and pain relief and project and experimental planning. Ask a layperson (friend, neighbour, relative) to read your application before submitting it. If they can't understand what you plan to do, do not assume the AEC members will.

IT Hints

The application form contains developer controls like check boxes, and drop down boxes. For these to work properly, you need to have the developer tab installed in your version of Word. Once working you only need to click on the boxes to make them checked, and click on the dropdown box to bring up the options. You don't need to highlight them, or place a cross next the box. For instructions on how to do this follow this link:
https://support.office.com/en-us/article/Create-forms-that-users-complete-or-print-in-Word-040c5cc1-e309-445b-94ac-542f732c8c8b

JAMES COOK UNIVERSITY
ANIMAL ETHICS COMMITTEE

APPLICATION FOR ANIMAL BASED RESEARCH

Please forward in hard copy: the original signed application form plus 1 copy to Noema Patterson, Research Office, Faculty Science & Engineering Building, DB017. An electronic copy of the application form and proposed animal usage spreadsheet must also be emailed to: ethics@jcu.edu.au

Animal Welfare Unit, Biosecurity Qld
DEEDI, Scientific Registration Number: 0013
Registered User: James Cook University

ANIMAL ETHICS NUMBER *(Office Use ONLY)* A

IF YOUR PROJECT TAKES PLACE INVOLVES:

LABORATORY OR ANIMAL FACILITY WORK: COMPLETE THE ORANGE SECTIONS

FIELDWORK: PARKS, COASTAL WATERS, CATTLE or SHEEP STATIONS, EXTERNAL AQUACULTURE ETC COMPLETE THE GREEN SECTIONS

IF IT INVOLVES BOTH TYPES OF WORK, COMPLETE BOTH GREEN AND ORANGE SECTIONS

WHEN COMPLETING THE APPLICATION, REFER TO THE AEC APPLICATION GUIDE
ALL RELEVANT SECTIONS OF THE APPLICATION MUST BE COMPLETED
INCOMPLETE APPLICATIONS WILL BE RETURNED TO THE APPLICANT

PART 1 – ADMINISTRATION AND COMPLIANCE

1	**Title of project**	The title of the project should be unique (unless the project is continuing from an earlier AEC approval) and if the project is covered by a grant, should be similar to the grant title. *JCU policy/procedure*
2	**Purpose Category** **What is the purpose of the project?** (Use drop-down box) (See Appendix 1 for explanation of the categories)	Primary ..... Purpose Category: This question relates to the main purpose of the project. As a part of the university's registration in Queensland we are required to report animal use under certain categories to the government regulators every year. The categories are the choice of the regulator and some do not fit exactly with every project so choose the closest category. We do not have a say in the categories, and cannot add or change them. https://www.daf.qld.gov.au/animal-industries/welfare-and-ethics/using-animals-for-scientific-purposes/recordkeeping-and-reporting-requirements/reporting-requirements-for-animal-ethics-committees-and-registrants

3 Personnel

Principal Investigator /Academic Supervisor

If the Principal Investigator is a student, complete the information below for their Supervisor in the project and the Supervisor becomes the person with ultimate responsibility for the oversight of the project, and so must sign in place of the Principal Investigator in the declaration.

3	**Title first and last names**	The Principal Investigator (PI) must be affiliated with the university (or agreed external organisations) in some way; that is either an enrolled higher degree student or a member of staff. If the PI holds an adjunct position with JCU then a letter confirming their adjunct status must be supplied to the Research

		Office. Other organisations can be given approval to use the JCU AEC but they need to develop an agreement with JCU and have their own registration with the Queensland regulator of animal research *JCU policy/procedure*			
	Qualifications				
	Phone		**Mobile**		
	Email				
	Discipline, school or organisation				
	What is your relationship to JCU? [1]				
	JC Number (if applicable)				
	Does this project contribute to a higher degree by research? If 'Yes' provide details of your supervisor and have your supervisor sign the declaration below.	No	Yes	If 'Yes', which degree (PhD, MSc etc)	
	Role What will be your role in the project?				
	Experience Outline your experience in the role/experience/species used or outline how you will be trained and supervised until competent.				

[1] *Indicate if the investigator is currently an **E**mployee or a **S**tudent of JCU, or a researcher who is **N**ot affiliated with JCU. If not affiliate with JCU, provide details of the organisation's QLD Animal Research Registration including registration number below under the signatures.*

Academic Supervisor Details (if applicable)

3	**Title first and last names**			
	Qualifications			
	Phone		**Mobile**	
	Email			
	Discipline, school or organisation			
	What is your relationship to JCU? [1]			

4 Co-investigators

Copy and paste more tables if required, or delete tables that are not used.

Co-investigator 1

3	**Title first and last names**				
	Qualifications				
	Phone		**Mobile**		
	Email				
	Discipline, school or organisation				
	What is your relationship to JCU? [1]				
	JC Number (if applicable)				
	Does this project contribute to a higher degree by research? If 'Yes' provide details of your supervisor and have your supervisor sign the declaration below.	No	Yes	If 'Yes', which degree (PhD, MSc etc)	
	Role What will be your role in the project?				

	Experience Outline your experience in the role/experience/species used or outline how you will be trained and supervised until competent.

Co-investigator 2

	Title first and last names				
	Qualifications				
	Phone		**Mobile**		
	Email				
	Discipline, school or organisation				
	What is your relationship to JCU? [1]				
	JC Number (if applicable)				
3	**Does this project contribute to a higher degree by research?** If 'Yes' provide details of your supervisor and have your supervisor sign the declaration below.	No	Yes	If 'Yes', which degree (PhD, MSc etc)	
	Role What will be your role in the project?				
	Experience Outline your experience in the role/experience/species used or outline how you will be trained and supervised until competent.				

Co-investigator 3

	Title first and last names				
	Qualifications				
	Phone		**Mobile**		
	Email				
	Discipline, school or organisation				
	What is your relationship to JCU? [1]				
	JC Number (if applicable)				
3	**Does this project contribute to a higher degree by research?** If 'Yes' provide details of your supervisor and have your supervisor sign the declaration below.	No	Yes	If 'Yes', which degree (PhD, MSc etc)	
	Role What will be your role in the project?				
	Experience Outline your experience in the role/experience/species used or outline how you will be trained and supervised until competent.				

4	**SOP List** If any SOPs have been referred to in this application, please list these SOPs below (the reference number is adequate)	
	• • •	• • •

5	**Duration of project** (more than 3 years can be requested if matched to a grant/funding source)	☐ 1 year	☐ 2 years	☐ 3 years
		☐ 4 years	☐ 5 years	

6	**Funding Source** Funding Source: The AEC needs to be sure the conduct of the project is feasible and will be carried out as outlined in the application. The Code requires that the AEC knows that there is enough money and resources to ensure it can be carried out from start to finish. Information on whether it is funded under a grant, through partnerships, or from organisation's recurrent funding/ongoing budget needs to be provided here. Code: 2.4.8 (xx)			
	Grant title			
	Funding Body		Duration	
	Fund Scheme		Value	$

7a	**Has this project been submitted to any other animal ethics committee?**	No ☐	Yes ☐
7b	**If 'Yes', which AEC was it submitted to and what was the outcome of the submission?**		
	Submission to other AECs: This question is necessary to determine whether a project has been submitted to another AEC at some stage, and if so what the outcome of that review was. There are legitimate reasons to apply to more than one AEC including collaborations, interstate or overseas work. If two AECs have approved the same project, then the AEC needs to establish an agreement with the other organisation which determines responsibilities of each organisation and their AEC with the aim that the work will all be appropriately supervised. The AEC would need to ensure that the projects described in each application were the same, and that any conditions made on the approval were consistent. Also, the AEC needs to know whether an application had been rejected previously, why and whether the new application had changed in response to the feedback provided. *Code: 2.7.4(xxii), 2.4.9, 2.6.8*		

8a	**Approvals, permits and biosafety – Does this project involve:**	Yes
	Work in a national park?	☐
	Wildlife?	☐
	Endangered or threatened species or populations?	☐
	Any genetically modified animals or vectors? (including knock-out or knock-in animals, transgenic animals, cloned animals or GM bacterial, fungal or viral vectors)	☐
	Release of any genetically modified organisms into the environment?	☐
	Any infectious agents?	☐
	Interstate work?	☐
	International work?	☐

8b	**If 'Yes' to any of the above, indicate whether any additional licenses, permits or approvals are being applied for** (eg OGTR, Biosafety Committee, DEHP etc)
	Approvals, permits and biosafety The Code requires that the project also comply with the regulations overseen by other groups such as WH&S and the Department of the Environment and Heritage (National Parks and Native animals), Office of the Gene Technology Regulator, marine and fisheries etc. In many cases, these other permits require an AEC approval before they can be issued, the AEC only needs to know that researchers are aware of these requirements and the application for these permits has at least been submitted. *Code: 2.4.8(xxi), 2.5.15(ix)*

9	**Collaborating Organisation(s)** Provide the names of any organisations collaborating in the project (if applicable)
	The Research Office needs to know of any collaborations with other organisations so it can determine whether agreements need to be put in place. It's also a requirement for JCU staff who are working on a project which is approved by another organisation to notify the AEC in writing of this work, even if JCU AEC approval isn't required. *Code: 2.7.4(xxii), 2.4.9, 2.6.8*

PART 2 – JUSTIFICATION

10	**Project Outline:** Please supply below a brief description of your project in LAY language. State the AIMS, CONTEXT and a brief overview of the METHODS of your proposed project. Providing information in the form of diagrams, tables or flowcharts can assist the AEC to understand the project, especially when it involves difficult concepts or complicated biology. Please DO NOT cut and paste answers from grant applications.
	In this question, the answer should provide an overview of the project including: Context and Background: Define the problem that this project aims to solve and the hypothesis to be tested. Place it in the context of previous research/teaching (by your group or others'). Indicate where this project fits into the overall scheme of finding a solution. If this project follows from, is related to or is a continuation of a other AEC approvals, you could give a very brief summary of the outcomes of that project to introduce the new project. Aims: Outline the aim(s) clearly. This can be done by numbering each one, or using dot points. The aims provide a basis for the AEC to understand your experiments (described later in the application), eg each aim may translate into one or more experiment or activity and so this sections help to justify what you plan to do to the animals. Methods: A brief description or overview of the experimental methods or activities can be provided in this question. The answer should explain how the project will achieve the aims provided above. You could include the possible outcomes if the hypothesis is true and the project is a success, and if the hypothesis was wrong.

11	**Potential Benefits:** Please outline below the potential benefits and significance of the results that may come from the project.
	Outline the benefits to humans, animals and/or the environment. Use this question to sell the project to the AEC. *Code: 1.3, 1.5, 2.3.4, 2.4.2, 2.4.8(iii), 2.7.4(ii)(iv)*

12	**Justification for the use of animals:** Please justify the use of animals in the study weighing the predicted scientific or educational value against the potential impact on the welfare of the animals. (Please ensure to justify any ethically contentious or potentially severe procedures).
	When reviewing a project the main ethical decision the AEC must make is whether the potential benefits that may result from the project justify the impact the project may have on the animal. Will the end justify the means? To do this, the AEC needs to know the benefits (previous question) and then consider whether they are sufficient to balance any negative effects the animals may experience. For example, a project may have the potential to cause pain in or possibly death of the animals but if it there's a possibility the results may be significant and of great benefit to society, then the AEC will consider the project to be justified. In this question, you need to address the potential impact of the project, outline how any negative impact will be minimised (pain relief, humane endpoint etc) and then explain why you think the benefits justify this impact. *Code: 1.3, 1.5, 2.3.4, 2.4.2, 2.4.8(iii), 2.7.4(ii)(v)(iv)*

13	**Replacement:** Please explain why you need these animals for the project. Are there any alternatives available? Why are these alternatives unsuitable?
	Animal research is permitted by society under certain conditions, one of which is that at all stages the principles of the 3Rs are applied. The first R is replacement, which means that before a project can be approved the investigator has considered whether the same aims can be met without having to use animals. The AEC can't approve a project if alternatives to animals are available. In this question you need to outline why you must use animals and, if a non-animal alternative is available, why this cannot be used in your project. In this question you need to say why you can't use iv vitro, human clinical trials, computer models, inanimate surgical models etc. Since the definition of 'animal' states that the animal must be living, cadavers of animals killed for other purposes or tissues from animals killed or sampled for other purposes is considered replacement. In some projects there may be a pilot or practice/training stages using cadavers, inanimate models and other methods of replacement. Even if you must use animals for the main part of the project, if alternatives are being used for some of the work then this

	constitute replacement and can be described here. The AEC looks favourably on projects where the investigators have employed at least some sort of replacement. If there is no possibility of replacement of animals then the reasons why animals must be used should be provided in this answer. *Code: 1.1(v)(a), 1.18-1.20, 2.1.5 (iii), 2.4.6(iii)(ix)(x), 2.4.19, 2.7.4(v)(a)(viii)(x)*

PART 3 – ANIMAL HOUSING, CARE AND HUSBANDRY

14	**Research Facilities or Sites:** Provide details of every location where living animals will be held or where animal procedures will take place.

There are two types of research and teaching carried out at JCU: the first is where animals are sourced (either from the wild, suppliers, internally bred or housed for other reasons) and they are housed in animal facilities designed for animal housing and research. Alternatively, the work may be field based using animals that are sourced from the wild or external production facilities such as cattle stations, aquaculture farms etc. These different types of research have an impact on animal housing and care, with not all questions being applicable in both circumstances. For this reason the two types are separated: if you are doing fieldwork, fill in the Green questions and lab work the yellow. Some projects involve a field component where animals may be trapped for research in a facility. In these cases both need to be completed.

Note: the facility manager has been directed by the AEC to not allow access or issue animals unless the AEC application itself, any amendments and approvals are provided to them.

Laboratory or Facility Work – click on the box to tick which facility(ies) you are using.

Fieldwork
Name/approx. location – provide a name of the location; this is just to identify it in our database and for reporting. It could be a specific name such as the name of a cattle station or pet shop or less specific such as a Tully Gorge National Park or an approximate range 'Queensland Coastal waters between Townsville and Cairns'.
Type of site – refers to the description, purpose or function of the site. For example it could be a cattle station, a marine research station, a field site, national park, private address, choose the closest answer.
Specific address or location – provide a more exact location of the site, this could include a street address, more specific location(s) within a national park, GPS coordinate (if applicable and known)
State – if in Australia, choose the appropriate state (we only have approval to work in Qld, WA, NT and NSW or other territories that don't have animal research legislation such as Ashmore Reef, Macquarie Island). If overseas, leave blank and fill in the country in the next question.
Country – for overseas work only, leave blank if Australia

As a part of our animal research registration and reporting to the regulator we need to supply a list of sites where animals were used for scientific purposes. The AEC also conducts regular site inspections which may be announced prior or unannounced and so the inspectors need to know where to find the research site.

Note: the facility manager has been directed by the AEC to not allow access or issue animals unless the AEC application itself, any amendments and approvals are provided to them.

Code: 2.1.7, 2.3.21, 2.6.4(iv), 2.4.8(xx)

Laboratory / Facility Work	
Townsville	
☐ Immunogenetics Research Facility	☐ AITHM Rodent Facility
☐ Small Animal House (Building 86)	☐ Bush House (Building 70)
☐ Building 87 Labs	☐ AITHM (Building 47) Labs
☐ Building 28 – Constant Temperature Rooms	☐ Building 28 Display
☐ Veterinary Precinct – Pens/paddocks	☐ Veterinary Precinct – Aquaculture
☐ MARFU	☐ Veterinary Precinct – Turtle Health Research Facility
☐ The Science Place – Ground Level	☐ The Science Place – Level 1
☐ The Science Place – Level 2	
☐ Townsville other (please specify and provide location)	
Cairns	
☐ Building E5 – Rodent Facility	☐ Building E4 – Rodent Facility
☐ Building E1 – Rodent Quarantine Room	☐ Building E1 – Aquarium
☐ Cairns other (please specify and provide location)	

External	
☐ Orpheus Island Research Station	☐ Fletcherview Station
☐ Lizard Island Research Station	☐ AIMS
☐ External other (please specify and provide location)	

Fieldwork – (Field sites, parks, external properties including farms, animal production facilities, external vet clinics etc)

Add more rows if required by unlocking the form and cut and paste

Name/approx. location Provide the name or general location of the site eg Gaslight Station, Rogers National Park, Ashmore Reef etc	**Type of site** Choose an option from the list that best fits the site (if more than one is	**Specific address or location** Provide details of the specific location or range eg GPS coordinates, street address, national park	**State** If in Australia, what state is the site in?	**Country** If not I Australis, what country is the site in?
	Type of Site		.	
	Type of Site		.	
	Type of Site		.	
	Type of Site		.	
	Type of Site		.	
	Type of Site		.	
	Type of Site		.	

Facility Manager Application Copy

If your project takes place in an animal facility, please provide a copy of your AEC application to the Facility Manager before submitting to the AEC to give them an opportunity to comment.

Laboratory / Facility Work	
15	**Source, transport and arrival (Commercially available species):** If the animals are sourced from a breeder or supplier: What is the source of the animals (source, suppliers, JCU breeding colonies)? How will the animals be transported to the facility/location where they will be housed? Describe how the animals will be acclimatised to the new housing before experiments begin – include period and any handling undertaken
	The AEC needs to know the details of where the animals will be sourced, and this may include biological/disease status of the animals before arrival, how the animals will be transported from the source to the research site (or between research sites) and how the animals will be treated on arrival including acclimation to the new housing and to procedures that will be conducted once the research/teaching starts. For example, if animals will be handled, restrained and be given oral medication as a part of research, then acclimating them to these procedures (using water) before the project starts will reduce the stress and associated effects on physiology that occurs when first exposed to these procedures. In general, the AEC requires animals to acclimatise to their new surroundings for at least 7 days, but this can be reduced in some circumstances if justified. **Lab/Facility Work** – For animals sourced from a breeding unit/supplier provide details of whichever is applicable: • Supplier name • Source name • Breeding colony AEC number • Transport company • Transport conditions • Acclimation period and plan (required even for animals rehoused within JCU) or if not possible justification for requesting acclimation period to be waived *Animal Source: 2.4.8(v), 2.4.32(i), 2.5.13(i), 2.7.4(vii)(b), 3.2.3, 3.2.4 (wildlife),* *Transport: Scope of the Code, Governing Principles (ii), 1.4, 2.3.18, 2.6.4 (iv)(v), 3.1.2, 3.1.9, 3.2.3, 3.2.5 – 8, 3.3.37 – 39 (wildlife), 3.4.3(iii), 4.10 (teaching), 4.1.4(iii),* *Arrival/acclimation: 3.2.10 – 11, 3.1.12*

Fieldwork	
16	**Source and transport (Field work):** If the animals are sourced from the wild: Outline where the animals will be captured/sourced and details of their transport (if applicable), and how they will be introduced into their new environment (if applicable)
	Fieldwork – For animals sourced from the wild provide details of • Location name where caught/trapped • If transported, details of transport method and how they will be housed during the trip • Acclimation to new housing at destination (if applicable) before research, or if not possible justification for requesting acclimation period to be waived *Animal Source: 2.4.8(v), 2.4.32(i), 2.5.13(i), 2.7.4(vii)(b), 3.2.3, 3.2.4 (wildlife),* *Transport: Scope of the Code, Governing Principles (ii), 1.4, 2.3.18, 2.6.4 (iv)(v), 3.1.2, 3.1.9, 3.2.3, 3.2.5 – 8, 3.3.37 – 39 (wildlife), 3.4.3(iii), 4.10 (teaching), 4.1.4(iii),* *Arrival/acclimation: 3.2.10 – 11, 3.1.12*

17	**Housing/Holding:** Describe the type of caging/holding systems to be used for the animals including dimensions, number of animals per unit, bedding, environmental enrichment and environmental conditions. If the project uses multiple types of housing for different parts of the project, describe each type including the reason for, and duration of holding in each. If animals are to be housed individually, provide a reason for this and outline measures to be taken to prevent any stress associated with this social isolation. **OR** Provide or refer to an SOP containing the above details (provide a link or SOP reference below)
	Provide a description of the standard (non-experimental) housing or holding systems including: • Housing/caging description • Dimensions • Number of animals in each unit, and if animals are housed individually, provide a reason for

	this • Type of bedding provided • Environmental enrichment provided • Environmental conditions of the housing and immediate surrounds If animals are housed in different housing at different times, describe each type. Many facilities have SOPs that cover the information required in this question. If this is the case, reference the SOP here. *Code: 1.4, 2.3.2(iv), 2.3.17-18, 2.4(ii), 2.4.1, 2.4.8(xi), 2.5(ii)(xi), 3.1.2, 3.2.13-23, 4.10-11*

18	**Husbandry, care and feeding:** Describe the husbandry and care of the animals including frequency of cleaning, type of food/water and frequency of feeding/watering, grooming and other aspects that contribute to the wellbeing of the animals. Describe how the entry of disease will be prevented eg infection control or quarantine. **OR** Provide or refer to an SOP containing the above details (provide a link or SOP reference below)
	Describe how the animals will be cared for including any cleaning or enclosures, disinfection, disease and infection control, feeding and watering. Include frequencies of the activities, types of feed, whether it's available *ad libitum* or not. *Code: 1.4, 2.3.18, 2.4(ii), 2.4.1, 2.5(ii), 2.5.14, 2.5.15(vi), 2.7.4(xi), 3.1.16, 3.2.13, 3.2.15, 3.2.17-18, 3.3.5, 4(ii), 4.10-11, 3.2.24-25, 3.3.36, 3.3.29*

Part 4 – METHODS AND EXPERIMENTAL DESIGN

Animal Details	
	Justification of choice of animal What is the reason for choosing the species/strain/genotype of animal(s) used in this project?
19	Give the reason you have chosen the species/strain/line/breed/sex/age of animal(s) to be used. This question is mainly intended for laboratory animals, however, it is a requirement of the code to ask it. It may seem obvious if you are researching a particular species of wildlife, but an answer is required even if it seems obvious. For GM mice, provide a reason for choosing the particular line(s) and background strain(s), what about that particular genetic modification(s) and/or strain that is significant to your research? *Code: 2.4.8(v), 2.7.4(vii)(a)*
	Welfare issues presented by choice of animal Does the animal you plan to use have any underlying animal welfare issues requiring special consideration? If so describe these and outline how their wellbeing will be provided for. Eg genetic modification that requires special diets, or native animals that need to be housed individually **OR** Provide or reference a Phenotype report for the GM strain of animal(s) you plan to use (provide reference below)
20	Welfare issues presented after choosing an animal type for your research, consider what may need to be provided to it in terms of its housing/feeding/care etc in order to ensure its wellbeing is supported. This particularly refers to anything additional to standard routine husbandry for the species as outlined in Question 17. The question mainly refers to GM animals where a genetic change may change the animal's physiology in a way that additional support is required for them to survive/breed. It could also refer to some wildlife, where intensive housing can be stressful. If there are no welfare issues arising from the use of the animals you have chosen, then 'The housing of this species does not raise any welfare issues, standard housing is adequate to support wellbeing' could be an example of an acceptable answer. *Code: 1.9(i), 2.4.6(iv), 2.4.8 (xi)-(xii), 2.5.2(iv), 3.1.1, 3.1.5-6, 3.1.9, 3.2.5, 3.3.24, 3.3.33*

Experimental Design	
	Describe the experimental design Including the groups, number of animals per group etc The answer here needs to show how you have come up with the numbers requested in the Animal Usage Spreadsheet. Do not describe the methods here.
21	Outline how the project and experiments are designed in terms of any treatment groups, animal numbers per group, number of replications. This question is mainly to summarise the experimental design and so help provide a basis for the animal numbers being requested. It is mainly relevant to projects where there is a testable theory being investigated. A table showing groups and other details is the best way to provide the information, rather than explaining it long hand in sentences. Don't provide descriptions of procedures or methods here, just an overview of the structure is required. NOTE: When animals are bred to supply other projects, this is a scientific purposes. So every animal born on a breeding protocol is counted as used, regardless of what happens to it later and needs to be reported in animal usage. If the animal is used later in another project it will be counted again under that use and reported, so animals need to be reported very time they are used. For educational projects outline student numbers, times a year the course/training is held, to help justify animal numbers. When animals are used in teaching or research intermittently (particularly larger animals), they are considered used each time they participate in each training session/class. For example, if there is a herd of 50 cattle that are used in a class that takes place 6 times a year, then the animal usage over the year will be 6 x 50(300), not 50. If animals are to be re-used within the same project or transferred to other projects the AEC needs to consider the cumulative effect of the use of the animal over the life of that animal. It may reduce the number of individual animals needed if you reuse animals several times for different purposes, but if this results on increase stress, pain or distress then the AEC may prefer that the animals aren't used more than once. Reuse is more common in larger animals, than in rodents. For wildlife research you may hope to catch as many animals as possible, but your numbers requested

	could be based on the types and numbers of traps set each night, factored with the number of nights and locations to survey. If you were to catch one animal in each trap every time a trap is set this would be the number requested. *Code: 2.4.8(x), 2.7.4(vi)(ix)*
22	**Animal Numbers – Proposed Animal Use Spreadsheet Must be Attached** **NB Please provide the total number of animals required over the whole project (not per year or per site)** A proposed animal use spreadsheet must be completed and attached to the application. The spreadsheet can be found under Resources, Downloads and Links on the animal ethics webpage.
	This spreadsheet comes from Biosecurity Queensland and is used for our annual reporting to the regulator. The categories for procedure are decided by the regulator, and are supposed to represent the impact the procedures have on the animals. In some projects different animals may be the subjects of different procedures with different impacts. Separate these impacts if this is the case, otherwise choose the highest impact if animals are subject to several procedures. Similarly the animal type is chosen by the regulator and cannot be changed or reclassified. For GM animals, use a separate row for each GM line. It's no longer acceptable to group them as wild-type, GM, non-GM or by background strain. Each line must be accounted for individually. Where multiple species of wildlife are to be used, each species should be accounted for if possible, although in some circumstances it may be adequate to group animals. *JCU ethics requirement*

Reduction	
23a	**Is this a repeat or continuation of a previous project?** Answers to these questions helps you address one of the 3Rs where only the minimum number of animals required to meet the aims can be used. Repeating research may be considered to be wasteful of animals, but sometimes research needs to be repeated for example, if results are disputed, for teaching purposes or in wildlife surveys where re-surveying an area is necessary to determine changes in populations.
23b	**What is the statistical basis for the numbers of animals requested in this project?** Eg group numbers, sample size etc Provide the basis for your groups sizes/animal numbers. For example, is it based on a power analysis, previous research using the same model. This is particularly important if you are requesting large numbers of animals or have large numbers of animals per treatment group.
23c	**Has a statistician reviewed or been involved in deciding the number of animals being used on this project?** If you consulted a statistician (meaning a qualified statistician) say so, as this is viewed positively particularly when large numbers of animals are requested, where group sizes may be large or where it's not clear why you have asked for the numbers of animals. **NOTE: If you haven't consulted a statistician the AEC won't view this negatively.** *Code: 1.1(v), 1.21-27, 2.3.41, 2.4.8(x)(xi), 2.7.4(ix)*

Methods	
24	**Provide a step-by-step description (in lay language) of what will happen to the animals during the project.** Include in this description the following: Details of any procedures, samples taken and methods of sample collection, measurements made, anaesthesia, time periods for each part of the project, dose and route of any pharmaceuticals and any potential side effects of these. For field work, include methods of trapping, catching, observation methods, animal handling, number of traps used per session etc **OR** Provide a timeline of the project and include SOPs for any procedures and other methods being used.
	Provide descriptions of all activities that take place from the start of the project to the end in chronological order. This includes acclimation periods and acclimation activities, sampling surgeries, any husbandry that is

part of the experimental design (eg metabolic cages/tanks, mazes, isolation etc).

Outline procedures in detail, or refer to an AEC approved SOP or attach an SOP if not approved yet. The following details should be provided in the descriptions.

Intervention	Checklist of information to be provided
Administration of substances	• Agent name • Dose in mg/kg • Route of administration • Method of restraint • Volume and/or concentration of agent • Frequency of administration • If injected – needle gauge • Any adverse effects that may be likely due to this particular agent eg known side effects or potential side effects (for experimental agents)
Sampling	• Sample type and reason for sampling • Sample site • Volume/mass • Frequency of sampling • Method of restraint • Provision of pain relief (if procedure is painful)
Surgical procedures	• Full procedure description • Anaesthesia/analgesia provision • Suture type and wound after-care • Failure rate (replacement rate or mortality rate)

Code: 1.15-16, 2.4.8(viii), 2.4.18, 2.7

Fieldwork	
25	**Is there a chance that any of the following may occur in the field where it may not be possible to apply for an amendment?** **1. Taking of voucher specimens** **2. Collection or use of species not contained in this application** **3. Use of methods not outlined in this application** See the JCU AEC Opportunistic Sampling, Vouchering and Amendments to Projects in the Field Policy
	Amendments to approved protocols must be approved by the AEC before the change can be instituted, HOWEVER, under some circumstances, when working in field locations, investigators may need to make an amendment to their approved methods. The AEC has a policy that outlines when, how and what may be considered allowable to make in the field, as long as the amendment is minor and there was no way that the AEC could be contacted first. If you think that this may occur in your project, and can predict what changes may be made in the field, then give the details here.

Refinement	
26	Identify and describe each step or procedure in this proposal that may compromise an animal's wellbeing. State how any potential adverse effects will be avoided or minimised, pain and distress will be avoided and the wellbeing of animals will be maintained. Details could include treatment with substances, including antibiotics, anaesthetics and analgesics as well as their dose and each route of administration. Provide a brief description of measures taken to prevent any adverse effects the research may have on the animals involved.
	If any of the steps or procedures in Q23 have the propensity to cause pain or distress, outline the actions you will take to prevent or minimise the pain/distress the animals may experience. Examples of refinement for certain activities might include: • Surgical procedures – administration of anaesthesia, pain relief, use of sterile surgical technique to prevent excess pain or post-surgical infection. • Trapping of wildlife – empty traps first thing in the morning, provide hydration, use ant

	repellent *Code: 1.15-16, 2.4.8(viii), 2.4.18, 3.1.1-19*

Animal Monitoring	
27	**How will animal wellbeing be monitored at each stage of the project including: post-arrival, during procedures and post-procedure?** Include the frequency of monitoring, what criteria will be monitored to determine the wellbeing of the animal and whether they are experiencing pain or distress, which aspects of the monitoring will be done by the researcher and which will be done by animal technicians.
	Animals need to be monitored for the duration of their time on a project and records need to be kept that document these observations. The monitoring plan needs to be sufficient to detect and signs of pain or distress, illness or injury at the earliest possible opportunity so that something can be done to reverse the situation. When developing a monitoring plan you should consider the following: • What activities or procedures are known to have a higher impact on the animals or result in side effects or risks of the animal experiencing pain/distress/infection/side-effects etc • In relation to the activities or procedures being undertaken, when is it most likely that these effects may occur, and for how long after could they be experienced • If there are different stages of the project where there are different degrees of risk, could the monitoring return to a less intensive • How the animals may act or react physiologically, physically or behaviourally as a result of these effects if they occur • What observations or measurements you would need to take in order to detect these changes or reactions • Who will be undertaking the monitoring? Will it be the investigators only? What role will animal care staff play? When describing how you will monitor your animals you should include the following details: • Frequency of monitoring – daily, twice daily, hourly • Level of monitoring – observe in cage, remove and handle to examine, restrain for more invasive measurements • Monitoring criteria – what aspects of the animals will be observed/measured eg activity, eating, drinking, surgical wounds or sutures, respiration rate, body weight, coat, mucous membrane colour etc • Duration of monitoring – if there are differing intensities of monitoring at various stages, outline when a decision is made to reduce or increase the intensity and for how long this may continue eg after surgery an animal may be monitored consistently until able to stand, then twice daily until the sutures are removed then daily *Code: 2.1.5(ii), 2.1.5(v)(c), 2.1.7(i)(a), 2.4.18(vi)(vii)(viii), 2.4.20, 2.4.31, 2.5.5 (ii)(iv), 2.5.11-13, 2.7.4(xv), 3.1.20-25*
	Please provide examples of the animal monitoring records or checklists when submitting this application.
	Records must be kept that document the animal's wellbeing. The AEC considers that unless there is a record of monitoring then it hasn't taken place, and this is a breach of the approval. Records should be based on the monitoring plan and so will differ depending on the species, procedures being undertaken, location of the research and number of animals in the study at any time. There must be a record for every animal from arrival until the end of the animal use. The most common form of monitoring record used is the checklist, but they can be kept electronically but they must be able to be made available to the AWO or AEC at any time. They are also an efficient way for investigators to communicate with animal care staff. For more information on monitoring see the JCU AEC website. Monitoring records must be provided to the AEC with the application or the application will not be approved. *Code: 2.1.5(ii), 2.1.5(v)(c), 2.1.7(i)(a), 2.4.18(vi)(vii)(viii), 2.4.20, 2.4.31, 2.5.5 (ii)(iv), 2.5.11-13, 2.7.4(xv), 3.1.20-25*

Endpoints and Contingency Planning

Laboratory or Facility Work	
28	**What criteria will be used to determine the animal use in the research will end in the following situations?** **a) Expected end of the animal's use in the teaching activity** eg Day 42, 5 weeks after tumour induction, immediately after samples are taken etc **b) Humane endpoints (an unexpected end of the animal's use in the research, determined when the animal's involvement must end for animal welfare reasons)**
	Humane intervention points or humane endpoints are a predetermined clinical sign or a set of adverse clinical signs that indicate that an animal has developed a degree of pain or distress that requires it to be euthanised, regardless of whether the scientific aim has been met. A humane intervention point is chosen purely with the wellbeing of the animal in mind and will mean the end of the animals use in that project, although it may not mean that the animal needs to be euthanised. Intervention points will be determined using signs of pain or distress for that species of animal but also need to take into account the scientific outcomes. Intervention points should be based on objective assessments or measurements of the animal and its physiology If an animal is experiencing pain or distress then it's likely to affect the validity of any results, and this should be taken into account when choosing these points. For more information on choosing appropriate intervention points see the JCU AEC website. *Code: 3.1.18–3.1.19, 3.1.26–3.1.28, 3.3.13, JCU Program of Veterinary Care*
Fieldwork	
29	**If any animals are injured during the fieldwork, what plans are in place for their treatment or euthanasia it is required?** eg Is there a local veterinarian that can receive the animals
	When working in the field with animals, there may not be the same access to equipment, animal care or veterinary services. Each location and type of animal will be different. While it might seem unlikely that anything would go wrong or nothing has ever gone wrong before, there needs to be plans in place in case something does go wrong and an animal is injured. This could include taking a means for euthanasia to the field sites, or researching local veterinarians or wildlife carers in the area. For livestock field trials, details of the veterinary practice used by the property must be provided to the AEC. *Code: 1.14, 2.1.5(v)(d), JCU Program of Veterinary Care*

Fate of animals/method of humane killing	
30a	**What will happen to the animals at the end of their time on the project?** eg returned to normal husbandry conditions, returned to farm, released, euthanised, kept in a laboratory or display
	Describe what will happen to the animals once the project is complete. It may be they are euthanized in order to collect samples, released back into the wild, returned or rehoused in their previous normal husbandry conditions (especially livestock), they could be rehomed as pets or kept to be reused in other projects. *Code: 3.4.1*
30b	**Have any of the animals been used previously and/or will any of the animals be reused in other projects in the future?** If so provide details of their previous and potential future use Outline how you will ensure the animals have recovered sufficiently in between use
30c	**If any animals are to be rehomed/rehoused or released following the project, what steps will be taken to ensure the animals ongoing wellbeing?** See the AEC's Rehoming, Sale, Relase and Reuse Policy
30d	**If animals are to be euthanised as part of the project or because they are seriously injured, how will this be done, where will it take place and who will carry this out?** Include details of the agent used, concentrations, dose, route of administration (Refer to the AEC Policy and Guidelines for the Humane Killing of animals use for scientific purposes for acceptable methods)

	OR Provide or refer to an SOP containing the above details (provide a link or SOP reference below)
	Describe the euthanasia method that could or would be used in this project. Even if there is no planned euthanasia you need to be prepared in case it is required, so need to have an answer here regardless of the intended outcome. Code: 2.1.5(v)(d), 2.1.7(i)(c), 2.5.6, 3.1.2, 3.3.45, 3.4.1
30e	**Could animal tissues or carcases be shared with or provided to other investigators to replace the use of living animals in their work?** (Replacement/reduction)
	The Code says: *'Where practicable, tissue and other biological material from animals being killed must be shared among investigators or deposited in a tissue bank for subsequent distribution.'* This question related to reduction/replacement where tissues or carcases could be used or shared by other researchers. Unless there is a good reason that these cannot be shared, then the answer should generally be 'Yes'. Code: 1.26, 2.4.24, 2.5.10, 2.7.4(x), 3.4.1(v)

PART 5 – DECLARATIONS

31 Principal Investigator/Academic Supervisor Declaration:

I declare that:

1. I will provide adequate project supervision, ensure animal health and wellbeing and oversee the conduct of all staff participating in the project such that I will take overall responsibility for all aspects of the conduct of the project;
2. Adequate resources are available for the conduct of the project;
3. I have read the most recent Australian Code of Practice for the Care and Use of Animals for Scientific Purposes and the Animal Care and Protection Act and Regulation. I am aware of and agree to meet the responsibilities set out in these documents;
4. All staff involved in this project have been read this application and appropriate legislation and Code and agreed to meet their responsibilities and directions from the AEC;
5. I will ensure that the scope of monitoring the wellbeing of the animals at all stages of their care and use in the project is clearly outlined and communicated to all parties;
6. I undertake to inform the AEC of any changes to the proposed procedures or details given in this form subsequent to its submission (including change of contact details) by submitting an Amendment Application;
7. I agree to submit the mandatory Animal Ethics Report that will be forwarded to me annually and provide a final report upon completion of the project;
8. This project complies with the policy on Animal Research Ethics within James Cook University;
9. The purpose of this project cannot be achieved by alternatives to the use of animals.

Name - Principal Investigator OR student's supervisor)	Signature	Date
Name – Academic Supervisor (if PI is a student)	Signature	Date
If the Principal Investigator/Supervisor named above is not affiliated with JCU, provide the QLD Animal Research Registration number:		

32 Dean of College/Delegate

I declare that:

1. I have read the application.
2. I am satisfied that the use of animals is justified on scientific grounds
3. I am satisfied the investigators have the appropriate authority from the organisation, qualifications, experience and resources to carry out this project and meet their responsibilities under the Animal Care and Protection Act and the Code.

Name	Signature	Date

JAMES COOK UNIVERSITY
AUSTRALIA

JAMES COOK UNIVERSITY
ANIMAL ETHICS COMMITTEE

ANIMAL ETHICS NUMBER A
(Office Use ONLY)

AEC MONITOR'S REPORT

AEC Application Title:			
Principal Investigator:			
General Comments:			
Part 1 – Administration and Compliance:			
Part 2 – Justification:			
Part 3 – Animal Housing, Care and Husbandry:			
Part 4 – Methods and Experimental Design:			
Part 5 – Personnel and Declarations:			

Please indicate your recommendation:	**Yes**	**No**
This application **requires the above issues to be addressed** before it can go to the AEC		
This application should be **approved:**		
This application should be **approved with the following comments, provisions and/or reservations:**		
This application should **not be approved** for the reasons listed above:		

Monitor Name		Review Date	

APPENDIX 1 - DETAILS OF ANIMALS TO BE USED:

Please read the list below to determine the category and purpose of use for the animals in your project.

Purpose Category

Scientific Purposes for which the Animals will be Used: Pick ONE category that BEST describes the main purpose of your project and use the dropdown box in **Question 4** to choose the appropriate category. Use the brief guide and the examples given to help categorise the procedure.

YOU DO NOT NEED TO HIGHLIGHT CATEGORIES HERE

Cat.	Description	Examples
1	**The Understanding of Human or Animal Biology** Using animals for activities that aim to increase the basic understanding of the structure, function and behaviour of animals and humans, and processes involved in physiology, biochemistry and pathology	Molecular biology studies, studies of hormone levels for reproductive physiology
2	**The Maintenance and Improvement of Human or Animal Health and Welfare** Activities that aim to produce improvements in the health and welfare of animals, including humans.	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
3	**The Improvement of Animal Management or Production** Activities that aim to produce improvements in domestic or captive animal management or production.	Developing an improved molasses/urea based supplement for cattle; Determining optimum stocking rate for a pasture; Evaluation of a calcium supplement for layer hens
4	**The Achievement of Educational Objectives** Activities carried out for the achievement of educational objectives. The purpose of the activity 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.	Animals used by veterinary schools to teach examination procedures such as pregnancy diagnosis or artificial insemination; Sheep used in shearing demonstration classes for students; Dogs used to teach animal care to TAFE students; Rats and toads used in schools for dissection classes; Animals used in agricultural colleges or schools to teach routine husbandry procedures
5	**Environmental Study** Activities that aim to increase the understanding of the animal's environment or its role in it, or aim to manage wild or feral populations. These will include studies to determine population levels and diversity and may involve techniques such as collection of voucher specimens, radio tracking or capture and release.	Fauna surveys for environmental impact studies; Research into methods to control feral animals
DPI & F Protocol AE P4 http://www.dpi.qld.gov.au/extra/word/aniamlwelfare/protocolaep4.doc		

APPENDIX 2 - DETAILS OF ANIMALS TO BE USED:

Please read the list below to determine the category of the procedure(s) of use for the animals in your project. These imply the degree of impact the project will have on any group of animals.

Category of Procedure: The procedure categories are intended to give some indication of the impact the procedure will have on the animals or a group of animals. Place the categories in the appropriate column in the Animal Use Spreadsheet (Question 22). Use the brief guide and the examples given to help categorise the procedure.

YOU DO NOT NEED TO HIGHLIGHT CATEGORIES HERE

Cat.	Description	Examples
1	**Observational studies involving minor interference** Animals are not interacted with or, where there is interaction, it would not be expected to compromise the animal's welfare any more than normal handling feeding etc. There is no pain or suffering involved	Observational study only such as photographing whales at close quarters; Breeding or reproductive study with no detriment to the animal; Behavioural study with minor environmental manipulation
2	**Animal unconscious without recovery** Animal is rendered unconscious under controlled circumstances (i.e. not in a field situation) with as little pain or distress as possible. Capture methods are not required. Any pain is minor and brief and does not require analgesia. Procedures are carried out on the unconscious animal that is then killed without regaining consciousness	No experimentation on living animals eg animals killed painlessly for dissection, biochemical analysis, in vitro cell culture, tissue or organ studies; Teaching surgical techniques on live, anaesthetised animals which are not allowed to recover following the procedure
3	**Minor conscious intervention without anaesthesia** Animal is subjected to minor procedures that would normally not require anaesthesia or analgesia. Any pain is minor and analgesia usually unnecessary, although some distress may occur as a result of trapping or handling	Injections, blood sampling in conscious animals; 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
4	**Minor operative procedures with recovery** Animal may be rendered unconscious 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 post-operative analgesia may be appropriate. Field capture using chemical restraint methods is also included here	Biopsies Cannulations Sedation/anaesthesia for relocation, examination or injections/blood sampling
5	**Surgery with recovery** Animal may be 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. Postoperative pain is usually considerable and at a level requiring analgesia.	Orthopaedic surgery Abdominal or thoracic surgery
6	**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.	Minor infection, minor or moderate phenotypic modification, early oncogenesis Polyclonal antibody production Antiserum production
7	**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 that is not quickly or effectively alleviated.	Major infection, major phenotypic modification, oncogenesis with pain alleviation Isolation or environmental deprivation for extended periods Monoclonal antibody raising in mice
8	**Qld DPI Approved ONLY– LD 50; Death as an endpoint** This category only applies in those rare cases where the death of the animal is a planned part of the procedure. NB Under the Act, there are restrictions placed on lethality studies such as LD50 tests or similar. Investigators must apply to the DPI & F director-General to carry out such tests, gain AEC approval and pay a fee of $500 before the activity can proceed. (Where predictive signs of death have been determined and euthanasia is carried out before significant suffering occurs, category 6 or 7 applies.) **Death as an end point does not include: death by natural causes; animals which are euthanased on completion of the project; animals which are killed if something goes wrong; animals killed for dissection or for use as museum voucher specimens; or accidental deaths.**	Lethality testing (LD50, LC50) Toxicity testing with death as a planned end point without euthanasia.