

# James Cook University Animal Ethics Committee Investigator Guide

<b>1. Introduction</b>	<b>2</b>
<b>2. What is scientific animal use and when is the ethical review of activities required?</b>	<b>2</b>
Working Interstate	3
Working Under the Approval of Another AEC	3
Working Overseas	3
Do my planned activities require ethical review?	4
<b>3. The James Cook University Animal Ethics Committee (See Chapter 2.2)</b>	<b>4</b>
The Executive Committee	5
<b>4. The JCU Connect Animal Ethics Team</b>	<b>5</b>
<b>a. Legislation – Scientific animal use</b>	<b>5</b>
<b>5. The Australian Code for the Care and Use of Animals for Scientific Purposes</b>	<b>6</b>
<b>6. Principles governing scientific animal use</b>	<b>6</b>
3Rs – Replacement, Reduction, Refinement	6
<b>7. Application procedures</b>	<b>7</b>
Animal Ethics Monitors	7
Submission of documents to the AEC	8
<b>8. Guide to the JCU AEC application form</b>	<b>8</b>
Standard Operating Procedures (SOPs)	9
Administration section	9
Purpose and procedure categories	9
Duration of project approval	10
Other legislation and permit requirements related to animal use	10
Justification	10
Animal housing, care and husbandry	11
Methods and experimental design	11
Signatures and declarations	13
General tips for applications:	13
Submission of applications and other documents to the AEC	13
<b>9. Application review and AEC decision-making</b>	<b>13</b>
Enquiries about the review outcome and appealing a decision	14
<b>10. Managing your project</b>	<b>14</b>
Amendments	14
Urgent amendments	14
Annual and Final Reports	14
Working in Animal Facilities	15
<b>11. Training and Declaration of Competency</b>	<b>15</b>

# James Cook University Animal Ethics Committee Investigator Guide

## 1. Introduction

JCU recognises the significant role animals play in the progression of human knowledge. JCU research projects use animals only when their use is justified and when no other alternatives are available.

All activities involving animals must only be conducted in line with University policy, compliance with relevant legislation and after approval by JCU's Animal Ethics Committee (AEC). Approvals are only issued if the potential benefits of the work are likely to outweigh the effects on the animals concerned.

This guide was developed to assist investigators in their understanding of the regulatory framework that governs the use of animals for scientific purposes and the JCU processes of obtaining ethical review, but investigators should also participate in training and read the *Australian Code for the Care and Use of Animals for Scientific Purposes* (the Code) and read Chapter 4 of the *Animal Welfare Protection Act*.

## 2. What is scientific animal use and when is the ethical review of activities required?

The Code requires that all use of animals for a scientific purpose is subject to ethical review, where the meaning of 'animal' and 'scientific purpose' are as defined in the Code and legislation; and this is regardless of the impact that research has on the animal (*See Code 'Definitions'*).

**Animal** – *“any live non-human vertebrate (that is, fish, amphibians, reptiles, birds and mammals encompassing domestic animals, purpose-bred animals, livestock, wildlife) and cephalopods.”*

And including *“a live pre-natal or pre-hatched creature as follows if it is in the last half of gestation or development a mammalian or reptilian foetus, an avian, mammalian or reptilian pre-hatched young an avian, mammalian or reptilian pre-hatched young, a live marsupial young.”*

**Scientific purpose** – *“all activities conducted with the aim of acquiring, developing or demonstrating knowledge or techniques in all areas of science, including teaching, field trials, environmental studies, research (including the creation and breeding of a new animal line where the impact on animal wellbeing is unknown or uncertain), diagnosis, product testing and the production of biological products.”*

At JCU animals that are held but not currently being used in a project and those held in displays or in laboratories also require AEC oversight to ensure an acceptable level of care, and a Display/Holding Application needs to be submitted. There are some exemptions to this, as outlined in the AEC's Policy: [The Use of Animals in Short-Term Displays and Demonstrations](#) and include displays such as in open day or demonstrations to school students.

### Activities involving animals that may not require ethical review

The following activities may be exempt from ethical review:

- The use of animal cadavers under certain circumstances;
- Practical work, work experience and on-the-job training;
- Agricultural extension work;
- Veterinary clinical teaching;

- Acts of veterinary science done as a part of an animal's clinical care;
- Use or re-analysis of tissues or data collected previously for another purpose.

If you feel your activities may be exempt from review, please email the ethics team for confirmation before commencing your work. This won't lead to a delay to your commencement as confirmation can usually be given straight away.

### **Working Interstate**

AEC approval is required for scientific animal use in all parts of Australia, but each state and territory has its own legislation related to the use of animals for scientific purposes. This means that approval from an AEC in one jurisdiction, does not necessarily cover work carried across state borders.

JCU has approval to carry out animal work in six Australian jurisdictions: Queensland, the Northern Territory, Western Australia, South Australia, New South Wales and Tasmania. JCU does not have approval to work in Victoria or the Australian Capital Territory. There are some minor differences in legislation in different states and territories, so researchers should familiarise themselves with the legislation in the jurisdiction(s) in which they will be working. If you are planning on doing research interstate or in a jurisdiction where JCU is not registered, please contact the ethics team for advice.

When working interstate you should carry a copy of your AEC approval notice and JCU's license/registration documents. The license/registration documents can be provided to you by the ethics office.

### **Working Under the Approval of Another AEC**

Investigators must notify the JCU AEC in writing if they are involved in collaborative studies using animals at another institution, or if they are named in an application to the AEC of another institution. This can be done in an email attaching a copy of the application and the approval from the other AEC(s). *(See Code 2.4.9)*

Except under special circumstances, work conducted at a JCU facility or campus will need to be conducted under a JCU AEC approval. If you plan to use or house animals on a JCU campus or research station under the approval of an external AEC, you need to notify the JCU AEC. Please contact the ethics office for advice.

Where there are collaborations between investigators from more than one institution, an agreement will need to be put in place between the JCU AEC and the AEC of the other institution(s). The ethics team will organise these agreements according to standard agreement templates, investigators won't need to be involved and organising these agreements won't delay the start of the project. *(See Code 2.6.4-7)*

### **Working Overseas *(See Code 2.6.9-14)***

Depending on the country where your project will be conducted, overseas research may require approval by the JCU AEC. The AEC may accept the approval of overseas activities if:

- If the AEC is satisfied that work and animal care will meet the principles of the Code, including being reviewed by an ethical review body similar to an AEC;
- Any facilities where the work will be conducted comply with the Code;
- The researchers also acquire any local regulatory requirements for the work;
- The work isn't being conducted overseas to avoid compliance with the Code.

If you plan to conduct research overseas and are unsure whether you need JCU AEC approval or if you have overseas approvals and want the AEC to decide whether they will accept this approval, email the ethics team with details of you proposed work and any approvals you have or will obtain already.

**Do my planned activities require ethical review?**

If you are unsure whether your planned activity is scientific animal use or requires ethical review, please contact the ethics team at [ethics@jcu.edu.au](mailto:ethics@jcu.edu.au) but please don't start the activities before you have received confirmation. Activities involving animals cannot commence until you have received formal notification of ethical approval or exemption.

**3. The James Cook University Animal Ethics Committee (See Chapter 2.2)**

Animal Ethics Committees (AEC) are committees constituted to conduct the ethical review of animal use. Their functions and membership are prescribed by law, and they oversee all aspects of animal care and use in science in Australia and by Australian-based investigators. AECs ensure that all work is done ethically, humanely and in compliance with legislation and the Code.

AECs have a challenging task, they need to be able to understand complex scientific concepts, technical procedures and activities and be able to apply this understanding to the effects that these activities have on the animals. They need to have a good understanding of the legislation and various regulations that they must also apply when they review submissions. As a group they need to understand animals and their welfare, signs of pain or distress and aspects of their care and husbandry.

Members are volunteers and they devote considerable time and effort fulfilling their roles on the committee, and JCU owes our ability to use animals in our scientific programs to these volunteers.

AEC members fall into one of the following Categories:

<p><b>Category A</b>— a person with:</p> <ul style="list-style-type: none"> <li>• Current veterinary registration or qualifications recognised for registration; and</li> <li>• Experience relevant to the institution's activities.</li> </ul>	<p><b>Category B</b>— a person with:</p> <ul style="list-style-type: none"> <li>• Substantial and recent experience in the use of animals for scientific animal use; and</li> <li>• A higher degree in research or equivalent experience.</li> </ul>
<p><b>Category C</b>— a person who:</p> <ul style="list-style-type: none"> <li>• Demonstrates commitment to, and experience in, furthering the welfare of animals; and</li> <li>• Is not employed by or otherwise associated with the institution; and</li> <li>• Is not currently involved in the care and use of animals for scientific purposes; and</li> <li>• Where possible, have active membership or endorsement by an animal welfare organisation.</li> </ul>	<p><b>Category D</b>— a person who:</p> <ul style="list-style-type: none"> <li>• Is not employed by or otherwise associated with the institution; and</li> <li>• Has never, either in their employment or past their undergraduate education, has never been involved in the use of animals for scientific purposes; and</li> <li>• Does not fit the requirements of any other category.</li> </ul>

Category C and D members are independent of the institution to remove any potential conflict of interest from their decisions, and as such they may not have a scientific background. For

this reason, it's important that these members are able to understand the contents of applications so these need to be completed using lay language.

If you're interested in becoming a member of the AEC you can submit an expression of interest to [ethics@jcu.edu.au](mailto:ethics@jcu.edu.au).

### **The Executive Committee**

The Executive Committee is a committee that consists of the Chair and one member from either Category C or D that can review certain documents outside of an AEC meeting. They cannot approve new applications, but can approve Amendments if they are minor and not likely to cause harm to the animals, including pain and distress (*see Code Section 2.2.23 and Amendments below*).

### **4. The JCU Connect Animal Ethics Team**

The animal ethics team consists of the Animal Ethics Officer (AEO) and the Manager, Animal Welfare and Research Ethics/Animal Welfare Officer. We aim to facilitate the ethical review process in an efficient and supportive manner.

The team is available to provide advice and assistance to investigators in their dealings with the AEC, including:

- Advice on planning and conducting ethical and compliant animal research
- Advice on the Code and legislation
- Processing of applications and other submissions to the AEC
- Pre-review of submissions to the AEC
- Provision of training in the ethical animal use, the Code and legislation
- Veterinary and animal welfare advice including animal examination (including post-mortem) and disease investigation, anaesthesia and surgical training

#### **a. Legislation – Scientific animal use**

Scientific animal use is regulated through legislation in Australia and each state or territory has their own legislation that covers this work. In Queensland, the legislation is the [Animal Care and Protection Act \(the Act\)](#).

The Act outlines how scientific animal use is regulated, including the role and administration of the regulator, the system for registering scientific users of animals, the powers of government inspectors and creates offences related to animal use. Importantly, the Act makes it an offence to use animals for scientific purposes unless:

- You are registered or working under the registration of a registered institution;
- You have the approval of an Animal Ethics Committee, that is also registered with the regulator;
- Any requirements of the committee in relation to the use of animals are complied with; and
- Your activities and actions comply with the *Australian Code for the Care and Use of Animals for Scientific Purposes*.

Thus, the Code becomes part of the legislation and regulatory framework. While each state and territory has their own legislation, they all include the Code in legislation in this way, meaning you must comply with the Code no matter where in Australia you work.

When working interstate, you should carry a copy of JCU's license/registration for that state or territory and your JCU AEC approval notice. For a copy of the JCU license/registration for the state where you will be working contact [ethics@jcu.edu.au](mailto:ethics@jcu.edu.au)

## 5. The Australian Code for the Care and Use of Animals for Scientific Purposes

The [Australian Code for the Care and Use of Animals for Scientific Purposes](#) (the *Code*) is a document that deals more closely with the conduct of activities using animals for scientific purposes. It is a code of conduct that is developed through public consultation, with input from major stakeholders including: the NHMRC, the ARC, the CSIRO, Universities Australia, the RSPCA and other animal welfare organisations as well as the general public.

While the Act outlines the overall regulatory framework, the *Code* outlines a set of principles to be followed when using animals for scientific purposes. It also outlines the responsibilities of all those involved including investigators and animal care staff. It outlines the operation and membership of AECs, prescribes what information the AEC needs to be provided in order to assess proposed animal activities, outlines review pathways for submissions to the AEC and provides more specific advice on certain types of activities such as breeding animals for research, genetically modified animals, wildlife, animals in teaching, surgical procedures, pain and distress, animal monitoring, humane killing and humane endpoints, animal care and animal facilities.

Investigators are expected to read and abide by the *Code*, and have a good understanding of those sections that relate specifically to their work, in particular:

- Governing principles (*Section 1*)
- Responsibilities of AECs (*Section 2.3*)
- Responsibilities of investigators (*Section 2.4*)
- Responsibility of animal carers (*Section 2.5*)
- The sections under the headings "*Responsibilities of Investigators*" in *Section 2.6*
- Animal wellbeing (*Section 3*)
- The care and use of animals for the achievement of educational outcomes in science (*Section 4*) *if using animals in teaching*
- Complaints and non-compliance (*Section 5*)

The *Code* also prescribes the external oversight of institutions using animals and their AECs, making it mandatory for an independent external review to take place at least every four years, and most regulators require a copy of the review reports. "*Section 6 "Independent external review of the operation of institutions"* describes the scope of the review, processes and responsibilities of the review panel. It is a requirement of our registration as an organisation that can use animals in science that we undertake these reviews and act on any findings.

## 6. Principles governing scientific animal use

Apart from ethical review there are several other principles the AEC will apply when reviewing animal activities.

### 3Rs – Replacement, Reduction, Refinement

The principles of the 3Rs are guiding principles for the ethical use of animals in science. They were outlined in *The Principles of Humane Experimental Technique* by M.S. Russell and R.L. Birch in 1959 and have since been almost universally adopted around the world. They aim to ensure that there is constant, ongoing improvement in the treatment of animals in science over time and a push to find ways to replace animal use wherever possible. Investigators and

the AEC, are required to apply the principles at every step of animal use, from planning to publication.

**Replacement** – Methods that avoid or replace the use of animals

The principle of replacement requires that wherever possible, if there is a non-animal alternative, it should be used with the hope that eventually, animals may not be needed at all (although this is unlikely for research involving wildlife or livestock).

**Reduction** – Methods that minimise the number of animals used in a project

When the use of animals is justified, researchers must ensure that they use the minimum number of animals necessary to achieve their aims.

**Refinement** – Methods that minimise any adverse impact on the animals and/or enhances their wellbeing. To address Reduction, investigators need to apply sound statistical methods when deciding on animal numbers, use non-lethal sampling methods in longitudinal studies, control variation between animals or share tissues and data with other researchers.

Refinement refers to any approach which avoids or minimises the actual or potential pain, distress and other adverse effects experienced at any time during the life of the animals involved, and which enhances their wellbeing. When addressing *Refinement*, investigators should consider the following two questions:

- **What can be done to prevent/minimise pain or distress?**
- **What could be done to improve the animal's lives and create more positive experiences?**

For more information on the 3Rs, visit the [NC3Rs website](#).

## **7. Application procedures**

The AEC meets monthly, except January, usually on the first Friday of the month. Submissions to the AEC need to be submitted at least 2 weeks before the scheduled meeting. On rare occasions, and only if there is a good reason, late applications may be accepted or urgent review may be arranged.

Investigators should always download the latest version of the application forms when beginning to write their application. The forms sometimes change due to changes in regulation or legislation and so applications on old versions may be sent back.

### **Advice for the preparation of your AEC application**

We strongly recommend that investigators learn and understand the principles of the *Code* and ethical use of animals in science before they begin planning their projects. This will improve the quality of your application and the chances it will be approved at the first review.

### **Animal Ethics Monitors**

Animal Ethics Monitors are appointed in each college to act as a source of advice and assistance to researchers and students. Their primary role is to pre-review applications and other submissions, and provide constructive advice to ensure that the submissions are of a quality that would facilitate their approval following ethical review. At the moment, having your AEC application undergo a monitor's review is not mandatory, but it is highly recommended. Please consult Monitor in your discipline for a review.

With support of the AEC and the JCU Connect Research Ethics Team, Animal Ethics Monitors:

- Are a point of contact and advice for researchers in their college on the planning and design of ethical human research
- Provide advice on planning and designing ethical human research projects
- Conduct pre-reviews of submissions for ethical review in order to ensure they are of an acceptable standard
- Provide advice to researchers in responding to feedback and issues identified in ethical review

When submitting your application to monitors for review, keep in mind:

- If you're a student, have your supervisor review your submission before it goes to the monitor
- Try to submit it to the monitor at least a week before the HREC meeting closing date to give them sufficient time to review and provide feedback
- Submit it before you have sought signatures, so that if changes need to be made, these can be made before the final sign-off

### **Submission of documents to the AEC**

All submissions for review by the AEC need to be emailed to the generic email address [ethics@jcu.edu.au](mailto:ethics@jcu.edu.au) to ensure they are not mislaid and will be processed in a timely manner. Documents should be signed, and the signature can be a wet signature, electronic or photo signature.

Attachments or other supporting documentation can be submitted, but any documentation must be in lay language, or summarised in lay language in the application itself.

### **8. Guide to the JCU AEC application form**

The JCU AEC has 5 application forms for different types of research that are designed remove or rephrase any redundant or irrelevant questions:

- Application for an Animal Research Project – for research projects;
- Application for an Animal Research Project (Observational field work) – for research that involves observational field work;
- Application for a Teaching Project – for animal teaching practicals and projects;
- Application for an Animal Breeding Program – for animals breeding colonies and breeding animals to supply research or teaching programs;
- Application for Animal Holding/Displays – for animals held by JCU staff or students in displays or on JCU property and not being used for scientific purposes.

Before completing the application form, researchers should:

- Read the *Code*;
- Read all appropriate guidance documents related to your discipline of research and research project;
- Feel free to contact the Animal Welfare Officer to discuss veterinary, compliance or animal welfare aspects of your proposed research;
- Undertake animal research ethics training;
- Undertake training in the procedures to be used in your projects and complete the appropriate Competency Declaration in LearnJCU to document that you're competent;
- Download the latest version of the forms from the AEC's *Resources, Downloads and Links* webpage.

The ethical review of your research will be guided by the *Code*, and decisions made will be based on this document, related guides, guidelines outlining best practice and the legislation.

For more advice on what information the AEC requires in each question please see the attached Application Guide

### **Standard Operating Procedures (SOPs)**

SOPs are documents that describe from start to finish how a procedure is done. They are tools that should be used in training staff to perform procedures and document when they are competent. Approved SOPs can be referenced in AEC applications, removing the need to describe the procedure and so reduce the administrative burden for investigators.

There are currently over 200 approved SOPs available to use, stored in LearnJCU organisation *Animal Welfare Organisation*. To access the organisation, you can self-enrol by clicking on *Tools* in the left sidebar, then choosing *My Organisations*.

If there is no SOP for the procedure you're needing to describe, you can write one and submit it to the AEC for approval with your application. If the description of the procedure is slightly different to how you would carry it out, you can still reference the SOP, but outline the differences in the AEC application.

When referencing a SOP you should include the full title as well as the number to make it easier for the AEC to understand what you are proposing to do.

SOPs cannot be used without being approved by the AEC, and to remain approved they must be reviewed every 3 years. If you do reference a SOP in your application, it is expected that you have read it and completed or are being training in the procedure. It's important to know the contents of the SOP before using it as if you do not follow the instructions in the SOP, you will be in breach of your AEC approval.

### **Administration section**

In this section provide details of the investigators working on the project, any conflict of interest or collaborations (*Code 2.1.8(iii), 2.6.4-7*).

All investigators involved in animal work need to be listed on the application and if anyone who isn't listed does work with animals, there will be a breach of the AEC approval.

The AEC can only approve an application if all investigators listed are trained and competent in the roles they will play in the project, or there is a plan to train and supervise the person until they are competent (*Code 1.29*). The AEC determines competency by reviewing the answers in the application and by referencing the training records and declarations of competency in LearnJCU "Animal Welfare Organisation". Therefore it's important that investigators have completed their competency declarations or else approval could be delayed.

### **Purpose and procedure categories**

Every year JCU reports its total animal use to regulators in each state. These are broken down based on the purpose of the research and the procedures undertaken in the research. The regulator then makes public the states combined animal use, which is important for transparency.

You are asked to choose one category each for the purpose and procedure drop down lists. The procedure category relates to the impact the procedures have on the animals. If, for procedure category, there are several procedures, choose the category that represents the highest impact (the impact generally increases as you go down the list). There should be only one procedure and one purpose category for each application, you do not need to differentiate between what is happening to any animals within that application.

For explanations of each category see the guides at the end of the application.

### Duration of project approval

Approvals for research and teaching projects is generally for a maximum of three years, but this is subject to the submission of satisfactory annual progress reports by the due date.

If justification can be provided and funding is available, approvals for up to five years can be given. Justification would include that 5 years of funding is available in the form of a five year grant.

### Other legislation and permit requirements related to animal use

As well as legislation related to the scientific use of animals, other legislation, permits and authorities may also apply, and you will be asked to confirm that other approvals have been obtained or been applied for in the application. These include:

Type of Work	Approval Required	Organisation to Contact
Parks and wildlife	Scientific Research and Educational Purpose Permit	<a href="#">Queensland Parks and Wildlife</a>
Genetically modified organisms	Notifiable Low Risk Dealing Licensed Dealing	<a href="#">JCU Biosafety Committee</a>
Workplace health and safety	Field work risk assessment	<a href="#">JCU WH&amp;S</a>
Great Barrier Reef Marine Park	GBRMP permit	<a href="#">Great Barrier Reef Marine Park</a>
Prescription and restricted drugs and poisons	Queensland Health Approval	<a href="#">Queensland Health Drugs and Poisons</a> <a href="#">JCU Drug and Poison Management</a>

Please note, some of the legislation governing approvals is state based and so different approvals will be needed in each state or territory in which the project will take place.

### Justification

For a project involving animals to be justified, it must:

- Obtain or establish significant information relevant to the understanding of humans or animals; or
- Maintain or improve human/animal health and welfare; or
- Improve animal management or production; or
- Obtain and establish information relevant to understanding, maintaining or improving the environment; or
- Achieve educational objectives.

In this section the questions are designed to allow the AEC to determine whether there is sufficient evidence to support the case that the animal use is justified as outlined in the *Code*.

In order for the AEC to be satisfied that a project is justified, there must be evidence that (Code 1.7):

- The project has scientific or educational merit (Code 1.5(i), Application Question 10);
- Will result in potential benefits for human, animals or the environment (Code 1.5(i), Application Question 11);
- How the 3Rs *Replacement* has been addressed – The use of animals is essential to achieve the stated aims, and there is no alternative to using animals (Code Sections 1.1(v)(a), 1.5(ii), 1.18-20), Application Question 13);
- The potential impact the project will have on the animals involved is justified by the potential benefits (Code 1.3, Application Question 12).

Tips for this section

- Provide your answers in lay language;
- Provide only a brief overview of the project here;
- If you do need to use scientific concepts or terminology, provide definitions or explanations either in the answer, or in a glossary;
- **Read and answer the questions**, and only provide the information requested, further details can be provided in the appropriate questions later on (do not provide detailed descriptions of the aims methods, and procedures in this section);
- Don't cut and paste your answers out of a grant application or research proposal;
- Use diagrams to help explain scientific concepts or terminology.

### **Animal housing, care and husbandry** (Code Chapter 3.2)

In this section describe how the animals will be housed, fed, watered and cared for as a part of their routine husbandry. Routine husbandry is not part of the project itself, and any changes to the animals routine housing or care related to the research or teaching project needs to be outlined in the methods section.

As with other aspects of the scientific use of animals, routine husbandry must be carried out by someone who is trained and competent. This can be either the investigators or animal care staff or both, but it must be clear who is responsible for the care of the animals at any one time. Animal care staff (including volunteers) conducting routine husbandry do not need to be listed on the AEC application as long as they are not participating in any reaching or teaching using animals.

### **Methods and experimental design**

In this section you need to provide information related to:

- Your choice of species and whether that species has any underlying ethical issues (mainly related to genetically modified mice where the modification may lead to clinical disease) (see Code Section 2.4.8(v));
- Justification for the number of animals you are requesting – there needs to be a reason for the numbers requested) in terms of the research design and statistical basis for numbers of animals per group (see Code Sections 1.5(iii), 1.21);
- How the 3Rs – *Reduction* has been addressed, including whether there is an opportunity for tissue sharing (see Code Sections 1.1(v)(b), 1.21-27)
- Detailed descriptions of what happens to the animals with enough detail for the AEC to understand what happens to any animal from start to finish. If animals are subjected to tests or procedures more than once, the AEC needs to know how many times they will be subjected to each and the time period in between. SOPs can be

used to describe a procedure but the titles and context of the procedure should be outlined in the application;

- How the 3Rs – Refinement has been addressed in terms of the methods described, eg pain relief, housing, environmental enrichment (*see Code Sections 1.28-30*);
- Outline how the animals will be monitored (*see Code Section 3.1.20* and what criteria will be used to determine the whether the animal is in pain or distress and needs to be removed from the project (humane endpoints) (*see Code Sections 3.1.26-28*);
- Outlined what will happen to the animals at the end of their use on the project. In general, the animals will either be:
  - Euthanised – outline the method of humane killing, which must meet the requirements of the Code (*see Sections 3.3.45 and the [JCU AEC's Humane Killing of Animals for Scientific Purposes Policy and Guidelines](#) for acceptable methods by species*);
  - Re-used – any reduction in the number of animals needs to be balanced against any adverse effects of this re-use taking into account the animal's lifetime experience (*see Sections 1.22, 1.24, 2.3.15*);
  - Released – if wildlife is to be released it needs to comply with the requirements of the Code and release cannot put the animals at risk (*see Code Sections 3.3.3-39, 3.4.4-5*);
  - Returned to normal husbandry conditions – if animals are to return to their normal herd or husbandry conditions (*see Code Sections 3.4.4-5*).

#### Tips for this section

- Read and answer the questions in the appropriate sections;
- Refer to the JCU AEC Guides on [Anaesthesia and Analgesia and Animal Monitoring and Humane Intervention Points/Endpoints](#) and other established guides to ensure your planned activities are best-practice (*see Code Sections 1.16, 2.4.8(viii)*);
- Use:
  - Pictures – to demonstrate equipment used, procedures to be undertaken,;
  - Tables – to describe animal numbers in terms of treatment groups;
  - Diagrams – to explain metabolic pathways and biological concepts and processes;
  - SOPs - to describe commonly used procedures
- Make sure you provide a step-by-step description of what will happen to the animals from start to finish and at each step think about how any impact each might have on the animals can be minimised (Refinement applied to each step);
- Don't cut and paste from a grant or research proposal as they aren't in lay language and don't provide the information needed by the AEC to assess your project against the requirements of the Code;
- Don't refer to publications or websites when describing procedures or concepts unless the part being described is also outlined in the application. References and webpages can be provided to support the use of a procedures but the AEC can't be expected to find and go through a publication. Websites can be used but since links can be broken and webpages content can change, they cannot be relied on to provide information;
- If your project is observational or a wildlife survey, you do not need to provide a list of species or their numbers, you can provide these numbers and species when reporting;
- Use/adapt one of the AEC's monitoring sheet templates and submit it with your application.

## Signatures and declarations

Everybody working on a project needs to be:

- Named on the application;
- Trained and competent, or be supervised and trained until they are competent (*see Code Sections 1.29, 2.4.4(v)-(vi)*),
- Willing to accept responsibilities outlined in the declaration and the Code (*see Code Section 1.31-32, 2.4.8(xviii)-(xxi), Chapter 2.4(investigators) Chapter 2.5(animal carers)*);
- Given a copy of the AEC application, and understand and agree to their roles in the project.

**It's extremely important that all people working with animals to understand their legal and ethical responsibilities and their responsibilities outlined in the Code Chapter 2.4(investigators) Chapter 2.5(animal carers), have read the application and understand their role in the project.**

The Principle Investigator (PI) is the person with ultimate responsibility for the conduct of the project and the care of animals, unless the PI is a student, in which case the person with primary responsibility will be the primary Supervisor of the student named on the application.

### General tips for applications:

- Use this guide and refer to the sections of the Code outlined in this guide when planning your project and writing your application;
- Proof read the application and ask others to review the application;
- Ask for a monitor to review the application;
- Seek advice from the Animal Welfare Officer

### Submission of applications and other documents to the AEC

Completed, signed documents should be submitted to the AEC by the meeting deadline. Meeting dates and submission deadlines are outlined on the [JCU AEC's webpages](#).

## 9. Application review and AEC decision-making

An AEC application can only be reviewed and approved at a quorate meeting of the AEC. The AEC will review the applications and:

- **Approve** – the project can commence.
- **Conditionally Approve** – the project is approved in principle, but either requires minor modifications or the AEC requires more information, clarification or answers to their questions before the project can be given final approval.
- **Defer** – the application requires major revisions or changes to the projects methods.
- **Not approved** – the project falls short of the requirements of the Code, is considered unethical or lacks scientific rigour.

The AEC makes their decision in the following ways:

- **Objectively/logically** – the application needs to meet the requirements of the legislation, the Code and JCU's policies and procedures;
- **Subjectively/emotionally** – the application needs to be ethically acceptable to the members, based on their life experience, education, personal values and philosophy.

Work cannot begin on a project and amendments cannot be instituted until the investigator has received an Approval Notification from the AEC (please note that a conditional approval notice is not notice of approval and work cannot commence until the final notice is received).

### **Enquiries about the review outcome and appealing a decision**

If you have any questions about the outcome of the review of an ethics submission or want to appeal a decision contact the ethics office to discuss the matter. It's best to put your questions or request for appeal in writing.

### **10. Managing your project**

Once your application is approved, you will need to conduct and manage your project according to the approved protocol, any conditions applied on it by the AEC and in line with the *Code*.

### **Amendments**

If you need to change any detail of your protocol you need to submit an [Application for Protocol Amendment](#) outlining details of the changes as well as any change it may have on the impact the project has on the animals.

Amendments need to be approved by the AEC at a meeting unless they are minor and not likely to cause harm to the animals, including pain and distress.

### **Urgent amendments**

If you need to make urgent amendments to a protocol, the amendment may be eligible for Executive Committee review outside of a scheduled meeting if the amendment is minor and there is a good reason for the urgent review. Examples of amendments that the AEC considers as minor include:

- Change to personnel;
- Time extensions of less than one year;
- Changes to administered substances where the new substance is administered in a similar way and has similar actions and side effects eg types of analgesia or anaesthesia;
- Minor experimental design changes with no effect on animal welfare;
- Changes to strain, breed or species where there is no change to welfare or conservation status;
- Where the change addresses one or more of the 3Rs;
- Addition or removal of research locations;
- Addition of new Genetically Modified lines of mice to a project.

For more advice on minor amendments see the [AEC's Operating Procedures](#).

To signal that you need urgent Executive review of an amendment, answer the question at the bottom of the amendment form and provide a reason for the urgency.

### **Annual and Final Reports**

The Code requires that investigators report on their progress and animal use annually and on the completion of their projects. JCU has reporting requirements to every jurisdiction in which it operates, so reports are due at the end of February for activities that took place the previous calendar year.

When reporting the animal numbers used, the following guidelines apply:

- The number of each animal type actually used (not proposed) for the activity during 1 January to 31 December 2019. This also includes control animals, by-catch and non-target animals;
- If the animal was used under different AEC approvals, report each use separately;
- Animals must be counted for each project approved by an AEC, however if the same animals are used repeatedly within an activity (e.g. teaching animal handling once a week), these animals are only counted once for the year;
- When the same animals are used in an approved activity over two or more calendar years, then their use must be reported for each separate year e.g. if 10 cattle were used during Oct 2019 to Feb 2020, 10 cattle must be reported in the 2019 report and the same 10 cattle must be reported again in the 2020 report – reflecting that the same number were used in both calendar years.

### **Working in Animal Facilities**

If your project involves you working in a JCU animal facility or research station you will be required to undertake an induction for that facility.

You will also need to get the signature of the Facility Manager before you submit your application. This is because the facility staff need to ensure that they can accommodate your project in their facility and to make sure any information about the housing and care of the animals is correct. This step can save you time in receiving your final approval, as any incorrect information in the application will need to be corrected after the meeting, delaying approval.

### **11. Training and Declaration of Competency**

The Code requires that all people working with animals are trained and competent to carry out their roles in the project, or is being trained and supervised by someone until they are competent (*see Section 1.29*). This competency needs to be documented in training records and available to the AEC when reviewing your application.

JCU has adopted a procedure-based competency program using SOPs, where the competency measures are outlined in the SOP. These SOPs are available in LearnJCU, and once you are competent, go into the SOP for the procedure and complete the competency declaration for that procedure.

# Animal Ethics Committee Application Form Guide



## 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](mailto: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

<b>1</b>	<b>Title of project</b>	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.  <i>JCU policy/procedure</i>
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<b>2</b>	<b>Purpose Category</b> <b>What is the purpose of the project?</b> (Use drop-down box) (See Appendix 1 for explanation of the categories)	<p style="text-align: center;">Primary .....</p> <p>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.</p> <p><a href="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">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</a></p>
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### 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.

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

<sup>1</sup> Indicate if the investigator is currently an **Employee** or a **Student** of JCU, or a researcher who is **Not** 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)

<b>3</b>	<b>Title first and last names</b>			
	<b>Qualifications</b>			
	<b>Phone</b>		<b>Mobile</b>	
	<b>Email</b>			
	<b>Discipline, school or organisation</b>			
	<b>What is your relationship to JCU? <sup>1</sup></b>			

#### 4 Co-investigators

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

##### Co-investigator 1

<b>3</b>	<b>Title first and last names</b>			
	<b>Qualifications</b>			
	<b>Phone</b>		<b>Mobile</b>	
	<b>Email</b>			
	<b>Discipline, school or organisation</b>			
	<b>What is your relationship to JCU? <sup>1</sup></b>			
	<b>JC Number (if applicable)</b>			

	<b>Does this project contribute to a higher degree by research?</b> If 'Yes' provide details of your supervisor and have your supervisor sign the declaration below.	No	Yes	If 'Yes', which degree (PhD, MSc etc)
	<b>Role</b> What will be your role in the project?			
	<b>Experience</b> Outline your experience in the role/experience/species used or outline how you will be trained and supervised until competent.			

### Co-investigator 2

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

### Co-investigator 3

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

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

<b>5</b>	<b>Duration of project</b> (more than 3 years can be requested if matched to a grant/funding source)	<input type="checkbox"/> 1 year	<input type="checkbox"/> 2 years	<input type="checkbox"/> 3 years
		<input type="checkbox"/> 4 years	<input type="checkbox"/> 5 years	

<b>6</b>	<b>Funding Source</b> 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	\$

<b>7a</b>	<b>Has this project been submitted to any other animal ethics committee?</b>	No <input type="checkbox"/>	Yes <input type="checkbox"/>
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<b>7b</b>	<b>If 'Yes', which AEC was it submitted to and what was the outcome of the submission?</b>
	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. The AEC also needs to be sure that they are not providing approval that constitutes duplication of a project that may allow increased animal use. 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.  <i>Code: 2.7.4(xxii), 2.4.9, 2.6.8</i>

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

<b>8b</b>	<b>If 'Yes' to any of the above, indicate whether any additional licenses, permits or approvals are being applied for</b> (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

	<p>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.</p> <p><i>Code: 2.4.8(xxii), 2.5.15(ix)</i></p>
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<p><b>9</b></p>	<p><b>Collaborating Organisation(s)</b> Provide the names of any organisations collaborating in the project (if applicable)</p>
	<p>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.</p> <p><i>Code: 2.7.4(xxii), 2.4.9, 2.6.8</i></p>

**PART 2 – JUSTIFICATION**

<b>10</b>	<p><b>Project Outline:</b> 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.</p>
	<p>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.</p> <p>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 section helps to justify what you plan to do to the animals.</p> <p>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.</p>

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

<b>12</b>	<p><b>Justification for the use of animals:</b> 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).</p>
	<p>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.</p> <p><i>Code: 1.3, 1.5, 2.3.4, 2.4.2, 2.4.8(iii), 2.7.4(ii)(v)(iv)</i></p>

<b>13</b>	<p><b>Replacement:</b> Please explain why you need these animals for the project. Are there any alternatives available? Why are these alternatives unsuitable?</p>
	<p>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</p>

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**

<b>14</b>	<p><b>Research Facilities or Sites:</b> Provide details of every location where living animals will be held or where animal procedures will take place.</p> <p>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.</p> <p>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.</p> <p><b>Laboratory or Facility Work</b> – click on the box to tick which facility(ies) you are using.</p> <p><b>Fieldwork</b>  <b>Name/approx. location</b> – 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’.  <b>Type of site</b> – 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.  <b>Specific address or location</b> – 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)  <b>State</b> – 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.  <b>Country</b> – for overseas work only, leave blank if Australia</p> <p>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.</p> <p>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.</p> <p><i>Code: 2.1.7, 2.3.21, 2.6.4(iv), 2.4.8(xx)</i></p>
<b>Laboratory / Facility Work</b>	
<b>Townsville</b>	
<input type="checkbox"/> Immunogenetics Research Facility	<input type="checkbox"/> AITHM Rodent Facility
<input type="checkbox"/> Small Animal House (Building 86)	<input type="checkbox"/> Bush House (Building 70)
<input type="checkbox"/> Building 87 Labs	<input type="checkbox"/> AITHM (Building 47) Labs
<input type="checkbox"/> Building 28 – Constant Temperature Rooms	<input type="checkbox"/> Building 28 Display
<input type="checkbox"/> Veterinary Precinct – Pens/paddocks	<input type="checkbox"/> Veterinary Precinct – Aquaculture
<input type="checkbox"/> MARFU	<input type="checkbox"/> Veterinary Precinct – Turtle Health Research Facility
<input type="checkbox"/> The Science Place – Ground Level	<input type="checkbox"/> The Science Place – Level 1
<input type="checkbox"/> The Science Place – Level 2	
<input type="checkbox"/> Townsville other (please specify and provide location)	
<b>Cairns</b>	
<input type="checkbox"/> Building E5 – Rodent Facility	<input type="checkbox"/> Building E4 – Rodent Facility
<input type="checkbox"/> Building E1 – Rodent Quarantine Room	<input type="checkbox"/> Building E1 – Aquarium
<input type="checkbox"/> Cairns other (please specify and provide location)	

External	
<input type="checkbox"/> Orpheus Island Research Station	<input type="checkbox"/> Fletcherview Station
<input type="checkbox"/> Lizard Island Research Station	<input type="checkbox"/> AIMS
<input type="checkbox"/> 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 in Australia, 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	
<b>15</b>	<p><b>Source, transport and arrival (Commercially available species):</b>            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</p> <p>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.</p> <p><b>Lab/Facility Work</b> – For animals sourced from a breeding unit/supplier provide details of whichever is applicable:</p> <ul style="list-style-type: none"> <li>• Supplier name</li> <li>• Source name</li> <li>• Breeding colony AEC number</li> <li>• Transport company</li> <li>• Transport conditions</li> <li>• Acclimation period and plan (required even for animals rehoused within JCU) or if not possible justification for requesting acclimation period to be waived</li> </ul> <p><i>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</i></p>

Fieldwork	
<b>16</b>	<p><b>Source and transport (Field work):</b>            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)</p> <p><b>Fieldwork</b> – For animals sourced from the wild provide details of</p> <ul style="list-style-type: none"> <li>• Location name where caught/trapped</li> <li>• If transported, details of transport method and how they will be housed during the trip</li> <li>• Acclimation to new housing at destination (if applicable) before research, or if not possible justification for requesting acclimation period to be waived</li> </ul> <p><i>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</i></p>

<b>17</b>	<p><b>Housing/Holding:</b>            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.</p>
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	<p><b>OR</b> Provide or refer to an SOP containing the above details (provide a link or SOP reference below)</p>
	<p>Provide a description of the standard (non-experimental) housing or holding systems including:</p> <ul style="list-style-type: none"> <li>• Housing/caging description</li> <li>• Dimensions</li> <li>• Number of animals in each unit, and if animals are housed individually, provide a reason for this</li> <li>• Type of bedding provided</li> <li>• Environmental enrichment provided</li> <li>• Environmental conditions of the housing and immediate surrounds</li> </ul> <p>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.</p> <p><i>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</i></p>

	<p><b>Husbandry, care and feeding:</b> 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.</p>
<b>18</b>	<p><b>OR</b> Provide or refer to an SOP containing the above details (provide a link or SOP reference below)</p> <p>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 <i>ad libitum</i> or not.</p> <p><i>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</i></p>

## Part 4 – METHODS AND EXPERIMENTAL DESIGN

Animal Details	
19	<p><b>Justification of choice of animal</b> What is the reason for choosing the species/strain/genotype of animal(s) used in this project?</p> <p>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?</p> <p><i>Code: 2.4.8(v), 2.7.4(vii)(a)</i></p>
	<p><b>Welfare issues presented by choice of animal</b> 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</p> <p><b>OR</b> Provide or reference a Phenotype report for the GM strain of animal(s) you plan to use (provide reference below)</p>
20	<p>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.</p> <p><i>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</i></p>

Experimental Design	
21	<p><b>Describe the experimental design</b> 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.</p>
	<p>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.</p> <p>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.</p> <p>For educational projects outline student numbers, times a year the course/training is held, to help justify animal numbers.</p> <p>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.</p> <p>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.</p>

	<p>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.</p> <p><i>Code: 2.4.8(x), 2.7.4(vi)(ix)</i></p>
22	<p><b>Animal Numbers – Proposed Animal Use Spreadsheet Must be Attached</b>  <b>NB Please provide the total number of animals required over the whole project (not per year or per site)</b></p> <p>A proposed animal use spreadsheet must be completed and attached to the application. The spreadsheet can be found under <a href="#">Resources, Downloads and Links</a> on the animal ethics webpage.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p><i>JCU ethics requirement</i></p>

<b>Reduction</b>	
23a	<p><b>Is this a repeat or continuation of a previous project?</b></p> <p>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.</p>
23b	<p><b>What is the statistical basis for the numbers of animals requested in this project?</b>  Eg group numbers, sample size etc</p> <p>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.</p>
23c	<p><b>Has a statistician reviewed or been involved in deciding the number of animals being used on this project?</b></p> <p>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. <b>NOTE: If you haven't consulted a statistician the AEC won't view this negatively.</b></p> <p><i>Code: 1.1(v), 1.21-27, 2.3.41, 2.4.8(x)(xi), 2.7.4(ix)</i></p>

<b>Methods</b>	
24	<p><b>Provide a step-by-step description (in lay language) of what will happen to the animals during the project.</b></p> <p>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.</p> <p>For field work, include methods of trapping, catching, observation methods, animal handling, number of traps used per session etc</p> <p><b>OR</b></p> <p>Provide a timeline of the project and include SOPs for any procedures and other methods being used.</p> <p>Provide descriptions of all activities that take place from the start of the project to the end in chronological order.</p>

<p>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).</p> <p>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.</p>	
<b>Intervention</b>	<b>Checklist of information to be provided</b>
<b>Administration of substances</b>	<ul style="list-style-type: none"> <li>• Agent name</li> <li>• Dose in mg/kg</li> <li>• Route of administration</li> <li>• Method of restraint</li> <li>• Volume and/or concentration of agent</li> <li>• Frequency of administration</li> <li>• If injected – needle gauge</li> <li>• Any adverse effects that may result from the administration of this particular agent eg known side effects or potential side effects of the drug in question or (if not known) related drugs (for experimental agents)</li> </ul>
<b>Sampling</b>	<ul style="list-style-type: none"> <li>• Sample type and reason for sampling</li> <li>• Sample site</li> <li>• Volume/mass</li> <li>• Frequency of sampling</li> <li>• Method of restraint</li> <li>• Provision of pain relief (if procedure is painful)</li> </ul>
<b>Surgical procedures</b>	<ul style="list-style-type: none"> <li>• Full procedure description</li> <li>• Anaesthesia/analgesia provision</li> <li>• Suture type and wound after-care</li> <li>• Failure rate (replacement rate or mortality rate)</li> </ul>
<p><i>Code: 1.15-16, 2.4.8(viii), 2.4.18, 2.7</i></p>	

Fieldwork	
<b>25</b>	<p><b>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?</b></p> <ol style="list-style-type: none"> <li><b>1. Taking of voucher specimens</b></li> <li><b>2. Collection or use of species not contained in this application</b></li> <li><b>3. Use of methods not outlined in this application</b></li> </ol> <p>See the JCU AEC Opportunistic Sampling, Vouchering and Amendments to Projects in the Field Policy</p>
<b>25</b>	<p>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.</p> <p>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.</p>

Refinement	
<b>26</b>	<p>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.</p> <p>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.</p>
<b>26</b>	<p>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:</p> <ul style="list-style-type: none"> <li>• Surgical procedures – administration of anaesthesia, pain relief, use of sterile surgical technique to prevent excess pain or post-surgical infection.</li> </ul>

	<ul style="list-style-type: none"> <li>Trapping of wildlife – empty traps first thing in the morning, provide hydration, use ant repellent</li> </ul> <p><i>Code: 1.15-16, 2.4.8(viii), 2.4.18, 3.1.1-19</i></p>
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<b>Animal Monitoring</b>	
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<b>27</b>	<p><b>How will animal wellbeing be monitored at each stage of the project including: post-arrival, during procedures and post-procedure?</b></p> <p>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.</p> <p>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.</p> <p>When developing a monitoring plan you should consider the following:</p> <ul style="list-style-type: none"> <li>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</li> <li>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</li> <li>If there are different stages of the project where there are different degrees of risk, could the monitoring return to a less intensive</li> <li>How the animals may act or react physiologically, physically or behaviourally as a result of these effects if they occur</li> <li>What observations or measurements you would need to take in order to detect these changes or reactions</li> <li>Who will be undertaking the monitoring? Will it be the investigators only? What role will animal care staff play?</li> </ul> <p>When describing how you will monitor your animals you should include the following details:</p> <ul style="list-style-type: none"> <li>Frequency of monitoring – daily, twice daily, hourly</li> <li>Level of monitoring – observe in cage, remove and handle to examine, restrain for more invasive measurements</li> <li>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</li> <li>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</li> </ul> <p><i>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</i></p>
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<b>Please provide examples of the animal monitoring records or checklists when submitting this application.</b>	
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	<p>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.</p> <p>Monitoring records must be provided to the AEC with the application or the application will not be approved.</p> <p><i>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</i></p>
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<b>Endpoints and Contingency Planning</b>	
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<b>Laboratory or Facility Work</b>	
<b>28</b>	<p><b>What criteria will be used to determine the animal use in the research will end in the following situations?</b></p> <p><b>a) Expected end of the animal's use in the teaching activity</b> eg Day 42, 5 weeks after tumour induction, immediately after samples are taken etc</p> <p><b>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)</b></p>
	<p>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.</p> <p>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.</p> <p><i>Code: 3.1.18–3.1.19, 3.1.26–3.1.28, 3.3.13, JCU Program of Veterinary Care</i></p>
<b>Fieldwork</b>	
<b>29</b>	<p><b>If any animals are injured during the fieldwork, what plans are in place for their treatment or euthanasia it is required?</b></p> <p>eg Is there a local veterinarian that can receive the animals</p>
	<p>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.</p> <p>For livestock field trials, details of the veterinary practice used by the property must be provided to the AEC.</p> <p><i>Code: 1.14, 2.1.5(v)(d), JCU Program of Veterinary Care</i></p>
<b>Fate of animals/method of humane killing</b>	
<b>30a</b>	<p><b>What will happen to the animals at the end of their time on the project?</b></p> <p>eg returned to normal husbandry conditions, returned to farm, released, euthanised, kept in a laboratory or display</p>
	<p>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.</p> <p><i>Code: 3.4.1</i></p>
<b>30b</b>	<p><b>Have any of the animals been used previously and/or will any of the animals be reused in other projects in the future?</b></p> <p>If so provide details of their previous and potential future use</p> <p>Outline how you will ensure the animals have recovered sufficiently in between use</p>
<b>30c</b>	<p><b>If any animals are to be rehomed/rehoused or released following the project, what steps will be taken to ensure the animals ongoing wellbeing?</b></p> <p>See the AEC's Rehoming, Sale, Release and Reuse Policy</p>
<b>30d</b>	<p><b>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?</b></p> <p>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)</p> <p>OR</p>

	<p>Provide or refer to an SOP containing the above details (provide a link or SOP reference below)</p> <p>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.</p> <p>Code: 2.1.5(v)(d), 2.1.7(i)(c), 2.5.6, 3.1.2, 3.3.45, 3.4.1</p>
30e	<p><b>Could animal tissues or carcasses be shared with or provided to other investigators to replace the use of living animals in their work?</b> (Replacement/reduction)</p> <p>The Code says:</p> <p><i>'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.'</i></p> <p>This question related to reduction/replacement where tissues or carcasses 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'.</p> <p>Code: 1.26, 2.4.24, 2.5.10, 2.7.4(x), 3.4.1(v)</p>

**PART 5 – DECLARATIONS**

**31 Principal Investigator/Academic Supervisor Declaration:**

<p>I declare that:</p> <ol style="list-style-type: none"> <li>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;</li> <li>2. Adequate resources are available for the conduct of the project;</li> <li>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;</li> <li>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;</li> <li>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;</li> <li>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;</li> <li>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;</li> <li>8. This project complies with the policy on Animal Research Ethics within James Cook University;</li> <li>9. The purpose of this project cannot be achieved by alternatives to the use of animals.</li> </ol>		
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**

<p>I declare that:</p> <ol style="list-style-type: none"> <li>1. I have read the application.</li> <li>2. I am satisfied that the use of animals is justified on scientific grounds</li> <li>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.</li> </ol>

Name	Signature	Date
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ANIMAL ETHICS NUMBER  
(Office Use ONLY)

A

**AEC MONITOR'S REPORT**

<b>AEC Application Title:</b>			
<b>Principal Investigator:</b>			
<b>General Comments:</b>			
<b>Part 1 – Administration and Compliance:</b>			
<b>Part 2 – Justification:</b>			
<b>Part 3 – Animal Housing, Care and Husbandry:</b>			
<b>Part 4 – Methods and Experimental Design:</b>			
<b>Part 5 – Personnel and Declarations:</b>			
<b>Please indicate your recommendation:</b>	<b>Yes</b>	<b>No</b>	
This application <b>requires the above issues to be addressed</b> before it can go to the AEC			
This application should be <b>approved</b> :			
This application should be <b>approved with the following comments, provisions and/or reservations</b> :			
This application should <b>not be approved</b> 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	<b>The Understanding of Human or Animal Biology</b> 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	<b>The Maintenance and Improvement of Human or Animal Health and Welfare</b> 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	<b>The Improvement of Animal Management or Production</b> 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	<b>The Achievement of Educational Objectives</b> 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	<b>Environmental Study</b> 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 <a href="http://www.dpi.qld.gov.au/extra/word/aniamlwelfare/protocolaep4.doc">http://www.dpi.qld.gov.au/extra/word/aniamlwelfare/protocolaep4.doc</a>		

## 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	<b>Observational studies involving minor interference</b> 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	<b>Animal unconscious without recovery</b> 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	<b>Minor conscious intervention without anaesthesia</b> 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	<b>Minor operative procedures with recovery</b> 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	<b>Surgery with recovery</b> 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	<b>Minor physiological challenge</b> 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	<b>Major physiological challenge</b> 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	<b>Qld DPI Approved ONLY– LD 50; Death as an endpoint</b> 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.) <b>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.</b>	Lethality testing (LD50, LC50) Toxicity testing with death as a planned end point without euthanasia.

